

FILED

December 27, 2021

**KAREN MITCHELL
CLERK, U.S. DISTRICT
COURT**

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the United States Department
of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 5:21-CV-00300-H

**DEFENDANTS' RESPONSE IN OPPOSITION TO
PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION**

TABLE OF CONTENTS

INTRODUCTION.....	1
BACKGROUND	3
I. The COVID-19 Pandemic Has Had Devastating Effects.	3
II. Safe and Effective Vaccines and Masks Are Widely Available in the United States.....	5
III. The Head Start Act Grants the Secretary the Authority to Issue Performance Standards Related to Health and Safety of Participants and Employees in Head Start.....	6
IV. Recent Developments Have Revealed an Urgent Need for Further Action to Protect the Health of All Involved in Head Start.	8
V. The Secretary Issued the Vaccination and Masking Rule to Protect the Health and Safety of All Involved in Head Start from the Transmission of SARS-CoV-2 in Head Start Facilities.	9
VI. The Present Controversy	10
STANDARD OF REVIEW	10
ARGUMENT.....	11
I. Plaintiffs Are Unlikely to Succeed on the Merits of Their Claims.	11
A. The Rule is Authorized by Statute.	11
1. The Plain Statutory Text Authorizes the Rule.	11
2. ACF Has a Long History of Rulemaking Related to Head Start Health Standards, Including Vaccine and Mask Requirements, to which Plaintiffs Have Never Objected.	15
3. Nothing in the Statute or the Nondelegation Doctrine Forecloses the Secretary’s Reading of the Statute.	19
4. Governments Have Historically Required Students and Educators to Obtain Vaccinations and to Employ Commonsense Measures to Prevent the Spread of Contagious Diseases.	23
B. The Rule is Not Arbitrary and Capricious.	24
C. The Rule Does Not Improperly Rely on Existing Regulations.	37
D. The Secretary Had Good Cause to Issue the Interim Rule Without Advance Notice and Comment.	40

E.	The Rule Complies with 42 U.S.C. § 9836a(a)(2).....	43
F.	The Rule Complies with the Treasury and General Government Appropriations Act of 1999.....	46
G.	The Rule Complies with the Spending Clause.....	48
H.	The Rule Does Not Violate the Tenth Amendment or the Anti- Commandeering Doctrine.....	49
II.	Plaintiffs Will Not Suffer Irreparable Harm Absent an Injunction.....	52
III.	The Balance of Equities and Public Interest Overwhelmingly Favor Denying an Injunction.....	55
IV.	Any Injunctive Relief Should Be Appropriately Limited.....	57
CONCLUSION.....		59

TABLE OF AUTHORITIES

CASES

<i>Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.</i> , 141 S. Ct. 2485 (2021)	19, 20, 21
<i>Alaska Airlines, Inc. v. Brock</i> , 480 U.S. 678 (1987)	57
<i>Alcaraz v. Block</i> , 746 F.2d 593 (9th Cir. 1984)	41
<i>Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez</i> , 458 U.S. 592 (1982)	53
<i>Am. Health Care Ass'n v. Burwell</i> , 217 F. Supp. 3d 921 (N.D. Miss. 2016)	19
<i>Am.'s Frontline Drs. v. Wilcox</i> , No. EDCV 21-1243, 2021 WL 4546923 (C.D. Cal. July 30, 2021)	56
<i>Arkansas v. Oklahoma</i> , 503 U.S. 91 (1992)	12
<i>Asbestos Info. Ass'n/N. Am. v. Occupational Safety & Health Admin.</i> , 727 F.2d 415 (5th Cir. 1984)	43
<i>Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.</i> , 462 U.S. 87 (1983)	28, 33
<i>Benning v. Georgia</i> , 391 F.3d 1299 (11th Cir. 2004)	49
<i>Big Time Vapes, Inc. v. FDA</i> , 963 F.3d 436 (5th Cir. 2020), <i>cert. denied</i> , 141 S. Ct. 2746 (2021)	23
<i>Brackeen v. Haaland</i> , 994 F.3d 249 (5th Cir. 2021), <i>cert. denied</i> , No. 21-380 (U.S. Sept. 8, 2021)	51
<i>Breniser v. Shinseki</i> , 25 Vet. App. 64 (Vet. App. 2011)	47
<i>Case v. Bowles</i> , 327 U.S. 92 (1946)	50
<i>Chambless Enters., LLC v. Redfield</i> , 508 F. Supp. 3d 101 (W.D. La. 2020)	55

<i>City of New York v. FCC</i> , 486 U.S. 57 (1988).....	25
<i>Clapper v. Amnesty Int’l USA</i> , 568 U.S. 398 (2013)	55
<i>COMPTEL v. FEC</i> , 978 F.3d 1325 (D.C. Cir. 2020).....	30
<i>Cornish v. Dudas</i> , 540 F. Supp. 2d 61 (D.D.C. 2008), <i>aff’d</i> , <i>Cornish v. Doll</i> , 330 F. App’x 919 (Fed. Cir. 2009)	56, 57
<i>Council of S. Mountains, Inc. v. Donovan</i> , 653 F.2d 573 (D.C. Cir. 1981).....	41
<i>Daimler Chrysler Corp. v. Cuno</i> , 547 U.S. 332 (2006)	57
<i>Deerfield Med. Ctr. v. City of Deerfield Beach</i> , 661 F.2d 328 (5th Cir. 1981)	54
<i>Dep’t of Com. v. New York</i> , 139 S. Ct. 2551 (2019).....	27, 29
<i>Donovan v. Vance</i> , --- F. Supp. 3d ---, 2021 WL 5979250 (E.D. Wash. Dec. 17, 2021)	56
<i>Enter. Int’l, Inc. v. Corporacion Estatal Petrolera Ecuatoriana</i> , 762 F.2d 464 (5th Cir. 1985)	52
<i>FCC v. Prometheus Radio Project</i> , 141 S. Ct. 1150 (2021).....	24, 26, 31, 37
<i>FDA v. Brown & Williamson Tobacco Corp.</i> , 529 U.S. 120 (2000)	21
<i>Flast v. Cohen</i> , 392 U.S. 83 (1968).....	52
<i>Florida v. Dep’t of Health & Human Servs.</i> , --- F. Supp. 3d ---, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021).....	54
<i>Florida v. Dep’t of Health & Hum. Servs.</i> , ---F.4th---, 2021 WL 5768796 (11th Cir. Dec. 6, 2021)	<i>passim</i>
<i>GEO Grp. Inc. v. Newsom</i> , 15 F.4th 919 (9th Cir. 2021).....	12

<i>Gill v. Whitford</i> , 138 S. Ct. 1916 (2018).....	57
<i>Gonzales v. Oregon</i> , 546 U.S. 243 (2006)	19
<i>Harris v. Univ. of Mass., Lowell</i> , ---F. Supp. 3d---, 2021 WL 3848012 (D. Mass. Aug. 27, 2021), <i>appeal filed</i> , No. 21-1770 (1st Cir. Sept. 28, 2021).....	56
<i>Hodel v. Va. Surface Mining & Reclamation Ass’n</i> , 452 U.S. 264 (1981)	51, 53
<i>Holland Am. Ins. Co. v. Succession of Roy</i> , 777 F.2d 992 (5th Cir. 1985)	52
<i>Holland v. Nat’l Mining Ass’n</i> , 309 F.3d 808 (D.C. Cir. 2002).....	58
<i>In re Huckfeldt</i> , 39 F.3d 829 (8th Cir. 1994)	40
<i>In re MCP No. 165, Occupational Safety & Health Admin.</i> , No. 21-4027, 2021 WL 5989357 (6th Cir. Dec. 17, 2021).....	27, 43, 50, 55
<i>Jacobson v. Massachusetts</i> , 197 U.S. 11 (1905).....	23
<i>Jifry v. FAA</i> , 370 F.3d 1174 (D.C. Cir. 2004).....	41
<i>Johnson v. Brown</i> , ---F. Supp. 3d---, 2021 WL 4846060 (D. Or. Oct. 18, 2021).....	56
<i>Jordan v. Fisher</i> , 823 F.3d 805 (5th Cir. 2016)	10
<i>K Mart Corp. v. Cartier, Inc.</i> , 486 U.S. 281 (1988)	57
<i>Kisor v. Wilkie</i> , 139 S. Ct. 2400 (2019).....	38, 39
<i>Klaassen v. Trs. of Ind. Univ.</i> , ---F. Supp. 3d---, 2021 WL 3073926 (N.D. Ind. July 18, 2021).....	55
<i>Klaassen v. Trs. of Ind. Univ.</i> , 7 F.4th 592 (7th Cir. 2021), <i>application for stay denied</i> , No. 21A15 (Aug. 12, 2021).....	22, 23

<i>Ky. Coal Ass’n v. TVA</i> , 804 F.3d 799 (6th Cir. 2015)	24
<i>Lake Charles Diesel, Inc., v. Gen. Motors Corp.</i> , 328 F.3d 192 (5th Cir. 2003)	10
<i>Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania</i> , 140 S. Ct. 2367 (2020).....	11, 20, 24
<i>Louisiana v. Becerra</i> , No. 21-30734, 2021 WL 5913302 (5th Cir. Dec. 15, 2021)	3, 58
<i>Madsen v. Women’s Health Ctr., Inc.</i> , 512 U.S. 753 (1994)	57
<i>Marshall v. Goodyear Tire & Rubber Co.</i> , 554 F.2d 730 (5th Cir. 1977)	58
<i>Mass Corr. Officers Federated Union v. Baker</i> , ---F. Supp. 3d---, 2021 WL 4822154 (D. Mass. Oct. 15, 2021)	56
<i>Mayweathers v. Newland</i> , 314 F.3d 1062 (9th Cir. 2002).....	48, 49
<i>Merck & Co. v. U.S. Dep’t of Health & Hum. Servs.</i> , 962 F.3d 531 (D.C. Cir. 2020).....	20
<i>Montanans for Multiple Use v. Barbonletos</i> , 568 F.3d 225 (D.C. Cir. 2009).....	43
<i>Mourning v. Family Publ’ns Serv., Inc.</i> , 411 U.S. 356 (1973)	11, 12
<i>Munaf v. Geren</i> , 553 U.S. 674 (2008)	10
<i>Murphy v. National Collegiate Athletic Ass’n</i> , 138 S. Ct. 1461 (2018).....	51
<i>N.C. Fisheries Ass’n, Inc. v. Gutierrez</i> , 518 F. Supp. 2d 62 (D.D.C. 2007).....	24, 33
<i>Nat’l Ass’n of Mfrs. v. Dep’t of Def.</i> , 138 S. Ct. 617 (2018)	11
<i>Nat’l Endowment for the Arts v. Finley</i> , 524 U.S. 569 (1998)	48

<i>Nat'l Fed'n of Indep. Bus. v. Sebelius</i> , 567 U.S. 519 (2012)	48, 52
<i>Nat'l Welfare Rts. Org. v. Mathews</i> , 533 F.2d 637 (D.C. Cir. 1976)	11
<i>New York v. Dep't of Just.</i> , 951 F.3d 84 (2d Cir. 2020)	52
<i>New York v. United States</i> , 505 U.S. 144 (1992)	49, 51
<i>Nken v. Holder</i> , 556 U.S. 418 (2009)	55
<i>Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.</i> , 14 F.4th 856 (8th Cir. 2021)	22, 23
<i>Okla. ex rel. Okla. Dep't of Pub. Safety v. United States</i> , 161 F.3d 1266 (10th Cir. 1998)	51
<i>Pennhurst State Sch. & Hosp. v. Halderman</i> , 451 U.S. 1 (1981)	48, 49
<i>Pers. Watercraft Indus. Ass'n v. Dep't of Com.</i> , 48 F.3d 540 (D.C. Cir. 1995)	26
<i>Printz v. United States</i> , 521 U.S. 898 (1997)	51
<i>Roman Cath. Diocese of Brooklyn v. Cuomo</i> , 141 S. Ct. 63 (2020)	42
<i>Sabri v. United States</i> , 541 U.S. 600 (2004)	50
<i>Sepulvado v. Jindal</i> , 729 F.3d 413 (5th Cir. 2013)	10
<i>Sorenson Comm'ns Inc. v. FCC</i> , 755 F.3d 702 (D.C. Cir. 2014)	42
<i>South Dakota v. Dole</i> , 483 U.S. 2030 (1987)	48
<i>Talleywhacker, Inc. v. Cooper</i> , 465 F. Supp. 3d 523 (E.D.N.C. 2020)	56

<i>Texas v. Biden</i> , ---F. Supp. 3d---, 2021 WL 3603341 (N.D. Tex. Aug. 13, 2021)	53
<i>Texas v. United States</i> , 14 F.4th 332 (5th Cir. 2021)	58
<i>Thorpe v. Housing Authority of City of Durham</i> , 393 U.S. 268 (1969)	11, 12
<i>Tigges v. Northam</i> , 473 F. Supp. 3d 559 (E.D. Va. 2020)	56
<i>TJM 64, Inc. v. Harris</i> , 475 F. Supp. 3d 828 (W.D. Tenn. 2020)	56
<i>Trump v. Hawaii</i> , 138 S. Ct. 2392 (2018)	58
<i>United States v. Comstock</i> , 560 U.S. 126 (2010)	49
<i>United States v. Emerson</i> , 270 F.3d 203 (5th Cir. 2001)	53
<i>United States v. Hatch</i> , 722 F.3d 1193 (10th Cir. 2013)	50
<i>United States v. Mikhel</i> , 889 F.3d 1003 (9th Cir. 2018), <i>cert. denied</i> , 140 S. Ct. 157 (2019)	49
<i>Utility Air Grp. v. EPA</i> , 573 U.S. 302 (2014)	21
<i>Va. ex rel. Cuccinelli v. Sebelius</i> , 656 F.3d 253 (4th Cir. 2011)	52
<i>Valdez v. Grisham</i> , ---F. Supp. 3d---, 2021 WL 4145746 (D.N.M. Sept. 13, 2021), <i>appeal filed</i> , No. 21-2105 (10th Cir. Sept. 15, 2021)	56
<i>Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.</i> , 454 U.S. 464 (1982)	50
<i>Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983)	24
<i>Whitman v. Am. Trucking Ass’ns</i> , 531 U.S. 457 (2001)	23

<i>Williams v. Brown</i> , ---F. Supp. 3d---, 2021 WL 4894264 (D. Or. Oct. 19, 2021).....	56
<i>Winter v. Nat. Res. Def. Council, Inc.</i> , 555 U.S. 7 (2008).....	10, 52
<i>Wise v. Inslee</i> , No. 2:21-cv-0288, 2021 WL 4951571 (E.D. Wash. Oct. 25, 2021).....	56

STATUTES

5 U.S.C. § 553.....	41
5 U.S.C. § 601 note	46, 47
5 U.S.C. § 805.....	43
5 U.S.C. § 808.....	43
42 U.S.C. § 264.....	20
42 U.S.C. § 9831 <i>et seq.</i>	41
42 U.S.C. § 9831	6, 13, 14, 57
42 U.S.C. § 9832	14, 16
42 U.S.C. § 9835	15
42 U.S.C. § 9836	48
42 U.S.C. § 9836a.....	<i>passim</i>
42 U.S.C. § 9840a	6, 48
42 U.S.C. § 9842	40
42 U.S.C. § 9843	14
Headstart, Economic Opportunity, & Community Partnership Act of 1974, Pub. L. No. 93-644, 88 Stat. 2291	7
Pub. L. No. 105-277.....	46

REGULATIONS

26 Tex. Admin. Code § 746.3609.....	16
26 Tex. Admin. Code § 746.3611.....	16

45 C.F.R. § 1302.42.....	17, 18, 38, 39
45 C.F.R. § 1302.47.....	17, 22, 38
45 C.F.R. § 1302.93.....	16, 39, 40, 50
45 C.F.R. § 1304.22.....	17
45 C.F.R. § 1304.3-3	7, 15
45 C.F.R. § 1304.3-4.....	2, 7, 15
45 C.F.R. § 1304.5	16
45 C.F.R. § 1306.35.....	16
45 C.F.R. § 1308 App'x (2015).....	15
36 Fed. Reg. 2531 (Feb. 5, 1971).....	41
61 Fed. Reg. 57,186 (Nov. 5, 1996)	2, 7, 16
81 Fed. Reg. 61,294 (Sept. 6, 2016)	16, 39
86 Fed. Reg. 63,418 (Nov. 16, 2021).....	54
86 Fed. Reg. 68,052 (Nov. 30, 2021).....	<i>passim</i>

UNITED STATES CONSTITUTION

U.S. Const. art I, § 8	48
U.S. Const. amend. X.....	49

OTHER AUTHORITIES

9 Wright, Miller & Kane, Federal Practice & Procedure: Civil 2D § 2948.1 (3d ed.).....	53
153 Cong. Rec. S14375-02, 2007 WL 3375993 (daily ed. Nov. 14, 2007).....	22
Ashley Fowlkes, Manjusha Gaglani, Kimberly Groover, et al., <i>Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021</i> , 70 Morbidity and Mortality Weekly Report 1167 (Aug. 27, 2021), http://perma.cc/5YKH-QYR4	6, 27
CDC, COVID-19 ACIP Vaccine Recommendations, CDC (Nov. 5, 2021), http://perma.cc/B2U6-GFYR	16, 17

CDC, “COVID-19 Guidance for Operating Early Care and Education/Child Care Programs,” Nov. 10, 2021, http://perma.cc/6VRE-FRTR	9, 33
CDC, COVID Data Tracker, http://perma.cc/4CNT-7SKN	3, 5, 12
CDC, COVID Data Tracker Weekly Review, http://perma.cc/JWM5-5SZ4	1
CDC, “Delta Variant: What We Know About the Science,” Aug. 26, 2021, http://perma.cc/4YRA-UWSP	4
CDC, “Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, Feb. 19, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm	35
CDC, “Omicron Variant: What You Need to Know,” updated Dec. 20, 2021, http://perma.cc/K9GN-KGG2	5
CDC, “Science Brief: COVID-19 Vaccines and Vaccination,” updated Sept. 15, 2021, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html	27
Forum on Child and Family Statistics, https://perma.cc/8EU9-V2HA	8
<i>Head Start Expands in Md. County Where Scandal Flared Two Years Ago</i> , Washington Post, http://perma.cc/RB7C-YP5B	8
HHS, Grant Policy Statement (Jan. 1, 2007), https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf	7
Megan Jehn, J. Mac McCullough, Ariella P. Dale, et al. Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks—Maricopa and Pima Counties, Arizona, July-August 2021, (Sept. 24, 2021), MMWR Morb. Mortal Wkly. Rep. 2021, http://perma.cc/Z9YT-3P28	4
Minimum Standards for Child-Care Centers, Texas Health and Human Services Commission (Nov. 10, 2021), https://www.hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/protective-services/ccl/min-standards/chapter-746-centers.pdf	17
Miranda J. Delahoy, Dawud Ujamaa, Michael Whitaker, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents—COVID-NET, 14 States, March 1, 2020-August 14, 2021, (Sept. 10, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; http://perma.cc/F535-GXNZ	4, 27

Richard Royall & Tsung-Shan Tsou, *Interpreting Statistical Evidence by Using Imperfect Models: Robust Adjusted Likelihood*, Journal of the Royal Statistical Society, Apr. 25 2003.....37

Safer Federal Workforce,
<https://perma.cc/5F9G-H24C>26

Tracy Lam-Hine T, Stephen A. McCurdy, Lisa Santora, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School—Marin County, California, May-June 2021, (Sept. 3, 2021), MMWR Morb. Mortal Wkly. Rep. 2021,
<https://perma.cc/27TA-622J>4

The White House, Path Out of the Pandemic,
<https://perma.cc/M4GG-HB2Q>.....9

INTRODUCTION

A deadly disease called COVID-19 has ravaged the nation. By the time the rule at issue here was published more than three weeks ago, SARS-CoV-2, the virus that causes COVID-19, had infected over 50 million people and claimed more than 800,000 lives in the United States. Those numbers continue to grow. *See* Centers for Disease Control and Prevention (“CDC”), COVID Data Tracker Weekly Review, <https://perma.cc/JWM5-5SZ4> (interpretive summary for Dec, 17, 2021). The highly transmissible virus can easily pass from person to person. As a result, the pandemic has been devastating for children and families alike. Fortunately, safe and effective vaccines are now approved or authorized for emergency use to protect against COVID-19.

The Secretary of Health and Human Services (the “Secretary”) reviewed the evidence and concluded that he must take urgent action to protect Head Start students and those interacting with them from infection. Head Start, a federal grant program, provides funding to aid school readiness for infants, toddlers, and pre-school aged children from low-income families. The COVID-19 pandemic has hit Head Start students and families particularly hard. Head Start students are under five, and thus cannot be vaccinated. Many of these students rely on the programs not just for educational purposes, but also for everyday needs such as meals, so program closures due to COVID-19 outbreaks have severe negative consequences beyond the classroom. To make matters worse, a majority of Head Start children and personnel are minorities, who are disproportionately impacted by COVID-19.

Congress has assigned the Secretary a statutory responsibility to protect the health and safety of Head Start students and personnel. To do so, the Secretary issued an Interim Final Rule, Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68,052 (Nov. 30, 2021) (the “Rule”), requiring that those interacting with Head Start students be vaccinated for COVID-19, or otherwise qualify for an exemption. These individuals are required to

be vaccinated (or to obtain the second shot of a two-dose regimen) by January 31, 2022, or to request an exemption from this requirement from their employer. The Rule also requires masking, effective immediately, for all Head Start students over two years old and those Head Start personnel who have contact with students. The Secretary issued the Rule on an emergency basis, and waived a comment period in advance of publication (though the comment period is currently open until December 30, 2021), because there was an imminent need to protect children against a spike in COVID-19 cases in the winter months. The Rule also anticipates the Office of Head Start's planned return to fully in person-services in January 2022. The Rule is therefore necessary to avoid further disruption to Head Start children's development and learning.

Plaintiffs—the State of Texas and Lubbock Independent School District (“LISD”)—seek a preliminary injunction to prevent the Secretary from enforcing the Rule. But they have not demonstrated that they are entitled to this extraordinary remedy. Most importantly, they are unlikely to succeed on the merits. The Secretary has express statutory authority to ensure that federal funds are used to protect the health and safety of Head Start students and personnel. He has exercised this authority for decades, including by promulgating regulations requiring Head Start participants to receive a slate of vaccinations, *see, e.g.*, 45 C.F.R. § 1304.3-4(2) (1975), and requiring that staff undergo health examinations and screenings, *see, e.g.*, Head Start Program, 61 Fed. Reg. 57,186, 57,210, 57,223 (Nov. 5, 1996). Similarly, here, the Secretary reasonably exercised that authority to arrive at the vaccination and mask Rule. He explained his determination that the Rule's ability to protect the health and safety of those in the Head Start program compelled him to act now. The Secretary accordingly took emergency measures to protect the health and safety of children in the coming weeks and months and to preserve their ability to access the critical resources that Head Start programs provide.

Plaintiffs also cannot meet their burden to demonstrate the remaining preliminary injunction factors. A regulation that amends the requirements for a discretionary grant awarded primarily to

localities cannot suffice to show irreparable harm to Texas's sovereign interests. And any other alleged harm to Head Start programs from staff departure is entirely speculative. The equities and public interest also weigh heavily against an injunction, which would undermine the public's significant interest in protecting the health of children and preserving their ability to obtain an education and receive the many other benefits that Head Start programs provide.

Finally, the relief Plaintiffs seek—a nationwide injunction—is uncalled for and contrary to binding Fifth Circuit precedent as current as eight days ago. *See Louisiana v. Becerra*, No. 21-30734, 2021 WL 5913302 (5th Cir. Dec. 15, 2021) (staying a universal injunction to an HHS vaccination requirement for Medicare and Medicaid facilities to the extent it applied to nonparties). For all of these reasons, Plaintiffs' motion should be denied.

BACKGROUND

I. The COVID-19 Pandemic Has Had Devastating Effects.

The novel coronavirus SARS-CoV-2 causes a severe acute respiratory disease known as COVID-19. 86 Fed. Reg. at 68,052. SARS-CoV-2 is primarily transmissible through exposure to respiratory droplets when one person is in close contact with another person who has COVID-19. As of December 2021, over 51 million COVID-19 cases and 800,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN> (cited at 86 Fed. Reg. at 68,052 n.6). COVID-19 has had a disproportionate effect on low-income and minority communities. 86 Fed. Reg. 68,054–56.

Because the virus that causes COVID-19 is highly transmissible, it readily spreads among unvaccinated individuals in classroom settings, even when infection control practices are followed. *Id.* at 68,053. Unvaccinated educators are at a much higher risk of infection and, therefore, pose a higher risk of transmitting the virus to young unvaccinated children in their care. *Id.* Studies have also shown that a lack of consistent mask usage in schools is associated with a higher risk of transmission. *See id.*

at 68,056 & nn.47–48 (citing Tracy Lam-Hine T, Stephen A. McCurdy, Lisa Santora, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School—Marin County, California, May-June 2021, (Sept. 3, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1214, <https://perma.cc/27TA-622J>; Megan Jehn, J. Mac McCullough, Ariella P. Dale, et al. Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks—Maricopa and Pima Counties, Arizona, July-August 2021, (Sept. 24, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1372–73, <https://perma.cc/Z9YT-3P28>). Transmission of SARS-CoV-2 in child care settings often leads to infection and hospitalization in family members, including family members who are more susceptible to the effects of COVID-19 due to age or underlying condition. *Id.* at 68,055. When a child or staff member tests positive or is exposed to someone who has tested positive for SARS-CoV-2, classrooms and school programs often must be closed for days or weeks to allow time to receive test results and for quarantining. *Id.* Closures impose hardship on Head Start children and families by preventing in-person attendance in Head Start, thereby impairing early learning and development and diminishing the ability of parents to work. *Id.*

In June and July 2021, an especially contagious strain of SARS-CoV-2 known as the Delta variant drove dramatic increases in COVID-19 case and hospitalization rates throughout the United States. *Id.* at 68,052 & n.4 (citing CDC, “Delta Variant: What We Know About the Science,” Aug. 26, 2021, <https://perma.cc/4YRA-UWSP>). The Delta variant is associated with a higher risk of hospitalization in children: From June to mid-August 2021, weekly COVID-19-related hospitalizations among children and adolescents were nearly five times higher than in the preceding months. *Id.* at 68,054 & n.26 (citing Miranda J. Delahoy, Dawud Ujamaa, Michael Whitaker, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents—COVID-NET, 14 States, March 1, 2020-August 14, 2021, (Sept. 10, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1255, <https://perma.cc/F535-GXNZ> (noting also that hospitalization among children ages four

and below increased tenfold)). Vaccination and mask usage remain effective mitigation strategies against the Delta variant. *Id.*

When the Secretary issued the Rule, there were troubling indications that a resurgence of the virus was coming in the forthcoming winter months. *Id.* at 68,058; CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN>. Respiratory viruses, like SARS-CoV-2, typically circulate more easily in cold weather, and the United States experienced a large spike in COVID-19 cases during the winter of 2020. 86 Fed. Reg. at 68,058. Indeed, since the Secretary issued the rule, the U.S. has seen a sharp increase in cases, *see* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN>, owing in part to the newly emergent Omicron variant, *see* CDC, “Omicron Variant: What You Need to Know,” updated Dec. 20, 2021, <https://perma.cc/K9GN-KGG2>.

II. Safe and Effective Vaccines and Masks Are Widely Available in the United States.

Currently, three manufacturers offer vaccines approved or authorized for emergency use in the United States by the Food and Drug Administration (“FDA”). *See* 86 Fed. Reg. at 68,052. These vaccines are manufactured by Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson), respectively. *Id.* On October 29, 2021, the FDA authorized the Pfizer-BioNTech vaccine for use in children ages five and up. *Id.* at 68,059. There is currently no vaccine available in the United States for children under the age of five. *Id.*

These vaccines are highly effective at preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. *Id.* at 68,054–55. The available evidence indicates that these vaccines offer strong protection against all known variants of the virus, including the Delta variant—particularly against hospitalization and death. *Id.* at 68,054. Recent studies indicate that the vaccines are eighty percent effective in preventing SARS-CoV-2 infection among frontline workers—more effective in practice than other protocols, such as regular testing. *Id.* at 68,059 & n.74 (citing Ashley Fowlkes, Manjusha Gaglani, Kimberly Groover, et al., *Effectiveness of COVID-19 Vaccines in Preventing*

SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021, 70 Morbidity and Mortality Weekly Report 1167 (Aug. 27, 2021), <https://perma.cc/5YKH-QYR4>).

Like all vaccines, COVID-19 vaccines are not 100 percent effective at preventing infection, and some breakthrough cases are expected among people who are fully vaccinated. However, the risk of developing COVID-19 remains much higher for unvaccinated than for vaccinated people, and therefore the presence of unvaccinated personnel are expected to lead to higher transmission to other Head Start personnel and students. *Id.* at 68,055 & n.74. Vaccinated people with breakthrough COVID-19 cases are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19. *Id.* at 68,059 (citing Fowlkes, et al., *supra*). Studies have also shown that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer opportunities for transmission. *Id.* at 68,059.

Because children under age five cannot receive a COVID-19 vaccine at this time, masking remains an important mitigation strategy, along with vaccination among older individuals with whom young children come in contact. *Id.* at 68,055.

III. The Head Start Act Grants the Secretary the Authority to Issue Performance Standards Related to Health and Safety of Participants and Employees in Head Start.

Head Start is a federal discretionary grant program that promotes school readiness in low-income children up to age five. *See* 42 U.S.C. § 9831. Children under age three are eligible for the related Early Head Start program. *Id.* § 9840a. The Head Start program began as a summer program and demonstration grant in 1964 as part of President Lyndon B. Johnson’s War on Poverty. The Community Services Act of 1974 included the Headstart–Follow Through Act, which conferred a more permanent nature on the program. Headstart, Economic Opportunity, & Community Partnership Act of 1974, Pub. L. No. 93-644, 88 Stat. 2291. The Head Start program is administered by the Office of Head Start (“OHS”), within the Administration for Children and Families (“ACF”)

of the Department of Health and Human Services (“HHS”). Head Start is a direct federal-to-local grant that does not pass through the state.

The Headstart–Follow Through Act required the Secretary of Health, Education, and Welfare (predecessor to HHS) to issue regulations prescribing standards for Head Start grantees. Pub. L. No. 93-644, § 8(a), 88 Stat. 2291, 2300. Since 1975, the Head Start Performance Standards have included comprehensive health screening for children. 45 C.F.R. § 1304.3-3(b)(4)–(5), 1304.3-4(2) (1975). Over the years, additional health-related performance standards have been added. And in 1996, HHS added health screenings for staff and regular volunteers. Head Start Program, 61 Fed. Reg. at 57,210, 57,223.

Because of the discretionary nature of Head Start grants, all participants necessarily agree to abide by the standards HHS sets when they voluntarily seek to join the program. *See* HHS, Grant Policy Statement, at I-1, I-3 to I-4 (Jan. 1, 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>. No one has a right to a Head Start grant, and no one has a right to attend a Head Start program. As a discretionary grant, the federal government maintains the authority to choose which entities receive grants. *See id.* Any entity that chooses to apply for and receives a Head Start grant agrees that it will meet the performance standards HHS imposes, even if those entities are school districts or educational institutions. *See id.*

Head Start is not a universal program, nor does it dominate early childhood care in the United States. There are currently 864,289 children enrolled in Head Start programs, 86 Fed. Reg. at 68,077¹, whereas there are 24.6 million children ages five and under in the United States, *see* Forum on Child

¹ Plaintiffs misread a chart in the Rule to conclude that over 2.6 million children are affected by the Rule. Br. 22. That figure actually refers to the days per week children attend in-person services. 86 Fed. Reg. at 68,077.

and Family Statistics, <https://perma.cc/8EU9-V2HA>. Many alternative pre-kindergarten programs are available. For example, LISD provides, in the same schools, pre-K services to Head Start children and non-Head Start children, the latter of whom are not subject to the Head Start standards or the Rule. *See* Compl. ¶ 26, ECF No. 1; Decl. of Kathy Rollo (Rollo Decl.) ¶ 2, ECF No. 1-3. Alternative options are also available to an entity or family that objects to the Head Start performance standards, including health standards such as the Rule. For instance, before the COVID-19 pandemic began, one Maryland school system determined that it could no longer maintain the standards set for Head Start, so it relinquished its grant and provided services through its own non-Head Start pre-K program instead. *See Head Start Expands in Md. County Where Scandal Flared Two Years Ago*, Washington Post, <https://perma.cc/RB7C-YP5B>; *see also* Pls.’ Br. in Supp. of Mot. for TRO & Prelim. Inj., ECF No. 8 (“Br.”), at 10 n.30 (reporting the same story).

IV. Recent Developments Have Revealed an Urgent Need for Further Action to Protect the Health of All Involved in Head Start.

As noted above, the emergence of the Delta variant over the summer months led to a dramatic spike in cases, hospitalizations, and deaths caused by COVID-19, a resurgence that has been driven by the spread of infection among the unvaccinated population. The Secretary’s initial policy approach after vaccines became available to the general population during the early months of 2021 was to encourage, rather than require, vaccination. 86 Fed. Reg. at 68,054. However, as the agency eventually determined, “uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families.” *Id.* The vaccination rate among Head Start personnel was estimated to be 77.1% on November 10, 2021. *Id.* at 68,070. In September 2021, the President announced his COVID-19 Action Plan, which set out a series of regulatory actions that federal agencies were planning to undertake in response to the pandemic. As relevant here, the announcement described HHS’s plans to require vaccinations for teachers and personnel in Head Start programs. The White House, Path Out of the Pandemic,

<https://perma.cc/M4GG-HB2Q> (last visited Nov. 24, 2021). On November 10, 2021, the CDC issued updated guidance to early childhood education and child care programs, which, among other things, recommended universal indoor masking for children ages two and older in these programs. 86 Fed. Reg. at 68,054 & n.27 (citing CDC, “COVID-19 Guidance for Operating Early Care and Education/Child Care Programs,” updated Nov. 10, 2021, <https://perma.cc/6VRE-FRTR>).

V. The Secretary Issued the Vaccination and Masking Rule to Protect the Health and Safety of All Involved in Head Start from the Transmission of SARS-CoV-2 in Head Start Facilities.

On November 30, 2021, ACF published the interim final rule at issue here. The Rule adds to the Head Start Performance Standards that all Head Start staff, volunteers, and contractors whose activities involve contact with or providing direct services to children and families (collectively, “Head Start personnel”) in classrooms must be fully vaccinated for COVID-19. 86 Fed. Reg. at 68,060. Under the Rule, all non-exempt personnel must receive the second dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine by January 31, 2022. *Id.* at 68,052. Non-exempt individuals must provide documentation of their vaccination status. *Id.* at 68,061. Exemptions from the vaccination requirement will be given to individuals “who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” *Id.* Each Head Start program must establish a process for reviewing and reaching a determination regarding exemption requests. *Id.* The Rule provides that exempt individuals must be tested for COVID-19 on a weekly basis. *Id.* at 68,053.

The Rule also adds to the Head Start Performance Standards a universal masking requirement consistent with CDC recommendations. *Id.* at 68,060. All individuals ages two and over must wear a mask indoors in any setting where Head Start services are provided and inside any vehicle owned, leased, or arranged by the Head Start program. *Id.* Exceptions are permitted for individuals when they are eating or drinking, for children when they are napping, and for certain individuals who cannot

wear a mask due to a disability. *Id.* Unvaccinated individuals are also required to wear a mask outdoors in crowded settings or during activities that involve sustained close contact with other people. *Id.* The masking requirement became effective immediately upon publication of the Rule. *Id.* The Secretary also concluded that there was good cause to waive the notice-and-comment process in rulemaking. *Id.* at 68,058–59.

VI. The Present Controversy

Plaintiffs now challenge the Rule, asserting claims purportedly arising under the United States Constitution, the Administrative Procedure Act (“APA”), and a variety of other statutes. Compl. ¶¶ 224–52. Plaintiffs filed their Complaint on December 10, 2021 and served it on Defendants on December 14, 2021. *See* Compl.; ECF No. 12. One day later, on December 15, 2021, Plaintiffs moved for a preliminary injunction and temporary restraining order. Pls.’ Mot. for TRO & Prelim. Inj., ECF No. 6. The Court then ordered expedited briefing, requiring Defendants to respond by December 23, 2021. ECF No. 11.

STANDARD OF REVIEW

“A preliminary injunction is an extraordinary and drastic remedy” that should “never be awarded as of right.” *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008) (citation omitted). A plaintiff may obtain this “extraordinary remedy” only “upon a clear showing” that it is “entitled to such relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The plaintiff must show (1) “a substantial likelihood of success on the merits,” (2) “a substantial threat of irreparable injury,” (3) “that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted,” and (4) “that the grant of an injunction will not disserve the public interest.” *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (quoting *Sepulvado v. Jindal*, 729 F.3d 413, 417 (5th Cir. 2013)). The plaintiff must “clearly carr[y] the burden of persuasion on all four requirements.” *Id.* (citation omitted); *see also, e.g., Lake Charles Diesel, Inc., v. Gen. Motors Corp.*, 328 F.3d 192, 203 (5th Cir. 2003).

ARGUMENT

I. Plaintiffs Are Unlikely to Succeed on the Merits of Their Claims.

A. The Rule is Authorized by Statute.

The vaccination and masking requirements fall within the Secretary’s “broad rule-making powers.” *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969); *see also Nat’l Welfare Rts. Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976) (referencing Congress’s “broad grant of power” to the Secretary); Br. 14.

1. The Plain Statutory Text Authorizes the Rule.

Like any other question of statutory interpretation, an analysis of an agency’s statutory authority “begins with the statutory text”—and, when the text is clear, it “ends there as well.” *Nat’l Ass’n of Mfrs. v. Dep’t of Def.*, 138 S. Ct. 617, 631 (2018) (citation omitted); *see, e.g., Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020). Here, the Secretary’s authority to adopt the Rule flows directly from the unambiguous text of the statute.

Congress charged the Secretary with adopting “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress vested the Secretary with broad authority to issue “such other standards as the Secretary finds to be appropriate” for Head Start agencies and programs. 42 U.S.C. § 9836a(a)(1)(E). Binding Supreme Court case law confirms the extent of the Secretary’s authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency “broad authority.” *Mourning v. Family Publ’ns Serv., Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted). More specifically, “[w]here the empowering provision of a statute states simply that the agency may ‘make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,’” the Court held that “the validity of a regulation promulgated

thereunder will be sustained so long as it is ‘reasonably related to the purposes of the enabling legislation.’” *Id.* at 369 (quoting *Thorpe*, 393 U.S. at 280–81). The same is true of statutes that authorize regulations as the Secretary finds to be “appropriate.” *See, e.g., Arkansas v. Oklahoma*, 503 U.S. 91, 105 (1992); *GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021) (“statutory language—‘appropriate’ and ‘necessary and proper’—is a hallmark of vast discretion” (footnote omitted)).

The vaccination and masking Rule is comfortably within the Secretary’s statutory authority under this standard. By requiring vaccines and masking for certain Head Start personnel and participants under certain circumstances and subject to exemptions, the Secretary was imposing an “administrative standard” that was “necessary” for the safe management of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), and it was also a standard “relating to the condition . . . of facilities” to ensure they do not become places of viral contagion, *id.* § 9836a(a)(1)(D). At a bare minimum, he was imposing a “standard[]” he found to be “appropriate” for the Head Start program. *Id.* § 9836a(a)(1)(E). As noted above, Congress created the Head Start program as a means to provide a healthy and safe learning environment for low-income children across the country. This measure was “appropriate” to protect student health. The agency began by noting a CDC report that showed that over 51 million COVID 19 cases and 800,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN> (cited at 86 Fed. Reg. at 68,052 n.6). It then explained that “vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission and in avoiding severe illness, hospitalization, and death.” 86 Fed. Reg. at 68,052 (footnote omitted). HHS went on to reason that “[g]iven that children under age 5 years are too young to be vaccinated at this time, requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19.” *Id.* at 68,055. HHS further noted that in addition to protecting individuals from COVID-19, the requirements will “reduce closures of Head Start programs, which can cause hardship for families, and support the Administration’s priority of

sustained in-person early care and education that is safe for children—with all of its known benefits to children and families.” *Id.* (footnote omitted). In short, the agency spelled out in great detail the connection between the Rule and the purposes of the Head Start Act.

Plaintiffs make much of the supposed limits of the phrase “program performance standards” in 42 U.S.C. § 9836a(1), arguing that it cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. But even under the Plaintiffs’ own definition of this term as “standards to measure a program’s quality and conditions in terms of administration, facilities, and education,” Br. at 16, the Secretary’s rule is authorized. Standards designed to keep students and personnel healthy and classrooms open clearly measure “a program’s quality and conditions in terms of administration, facilities, and education.” *See* 86 Fed. Reg. at 68,056–57 (describing how school closures harm Head Start participants).

In any event, Plaintiffs fundamentally misunderstand the nature of the Head Start program, which was not intended to be limited to setting academic performance standards, but also geared toward improving the health and safety of impoverished children and their families and addressing all facets of students’ readiness to succeed in an academic setting. *See* 42 U.S.C. § 9831(2) (“It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development . . . through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.”).

Plaintiffs turn to dictionaries and case law related to other statutes to support their argument, but they ignore the Head Start Act itself. In fact, although Plaintiffs are correct that the act does not explicitly define “program performance standards,” the Secretary is charged with issuing deficiencies when programs fail to follow “program performance standards.” *Id.* § 9836a(e)(1). The act defines a “deficiency” as “a systematic or substantial material failure of an agency in an area of performance

that the Secretary determines involves—(i) a threat to the health, safety, or civil rights of children or staff; [or] (iii) a failure to comply with standards related to early childhood development and health services” *Id.* § 9832(2)(A). By its plain language, then, the Secretary can certainly establish “standards related to early childhood development and health services” and “the health . . . of children or staff” because he can issue deficiencies on failures to follow standards that are a threat to health and safety. *Id.* § 9836a(e)(1).

Numerous provisions in the Head Start Act charge the Secretary with the responsibility to issue regulations, as he deems necessary, to protect the health and safety of program participants and personnel. The statutory provisions show that the health of children is a relevant consideration in the broader context of the statute. The purpose statement explains in relevant part that “[i]t is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development—through the provision to low-income children and their families of health . . . services that are determined, based on family needs assessments, to be necessary.” *Id.* § 9831(2). Additionally, the Head Start Act directs that funding be used by Head Start agencies to provide “intensive training and technical assistance” for “[a]ctivities . . . to support . . . health services, and other services necessary to address the needs of children enrolled in Head Start programs.” *Id.* § 9843(d)(1)(G).

Other provisions are similarly in accord. *See id.* § 9832(21)(G)(i) (defining the “professional development” of “Head Start teachers and staff” that the act is intended to promote to include “activities that . . . assist teachers with . . . the acquisition of the content knowledge and teaching strategies needed to provide effective instruction and other school readiness services regarding . . . physical health and development”); *id.* § 9843(a)(3)(B)(xii)(VI), (b)(2)(D) (instructing the Secretary “to the maximum extent practicable” to “assist Head Start agencies and programs to address the unique needs of programs located in rural communities, including . . . removing barriers to obtain health

screenings for Head Start participants in rural communities” and also to “support training for personnel . . . to recognize common health . . . problems in children for appropriate referral”).² *See also id.* § 9835(m)(2) (directing the Secretary to establish rules requiring Head Start agencies to allow families of homeless children to apply to, enroll in, and attend Head Start programs while required documents, such as . . . immunization and other medical records . . . are obtained within a reasonable time frame”); *id.* § 9836a(a)(2)(C)(ii) (requiring the Secretary to consider the effects of any revisions in Head Start standards on the “quality, scope, or types of health . . . services required to be provided under such standards as in effect on December 12, 2007”).

2. ACF Has a Long History of Rulemaking Related to Head Start Health Standards, Including Vaccine and Mask Requirements, to which Plaintiffs Have Never Objected.

The first Head Start Program Performance Standards were issued in 1975, and they included comprehensive health screening that “should be carried out for all of the Head Start children,” including tests for anemia and tuberculosis as well as urinalyses. 45 C.F.R. § 1304.3-3(b)(4)–(6) (1975). Head Start staff were also required to verify immunizations records, *id.* § 1304.3-3(b)(8) (1975), and participants were required to complete all recommended immunizations, including for diphtheria/pertussis/tetanus, polio, rubeola, rubella, and mumps. 45 C.F.R. § 1304.3-4(2) (1975). Those requirements have evolved over the years in response to the most pressing health and medical threats of the times. For example, in the 1990s, guidance as an appendix to the performance standards included the appropriate treatment of children with HIV. 45 C.F.R. § 1308 App’x (2015). In 1996, HHS added health examinations for staff and tuberculous screening for staff and regular volunteers to the Head Start Program Performance Standards. 61 Fed. Reg. at 57,210, 57,223. And in response

² Those “rural communities” in which Congress intended the Secretary to take the most direct action regarding health measures certainly include many within Texas, a state that Plaintiffs acknowledge has a “largely rural character.” Br. 54.

to suggestions in comments that it no longer made sense to single out tuberculous, HHS revised the staff health standard in 2016 to include more general language about staff health and communicable diseases. Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,357 & 61,433 (Sept. 6, 2016). Up through 2015, HHS even specifically mandated vaccinations for pets of families with children enrolled in home-based Head Start programs. 45 C.F.R. § 1306.35(b)(2)(ix) (2015).

As noted above, health and wellness standards apply to staff, who are required to have “an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate.” 45 C.F.R. § 1302.93(a). And, most notably, all Head Start personnel are required to meet the child care standards of the states in which they operate. 42 U.S.C. § 9837(c)(1)(E)(iii); *see also id.* § 9832(2)(A)(vi) (defining a program deficiency in part as the “failure to meet any other Federal or State requirements that the agency has shown an unwillingness or inability to correct”); 45 C.F.R. § 1304.5(a)(viii) (specifying that failure to abide by applicable state requirements is a ground for termination). Texas’s Minimum Standards for Child-Care Centers require child care programs to develop a policy requiring staff to be vaccinated against “vaccine-preventable diseases” and for exempted employees to follow additional protective procedures “such as the use of protective medical equipment, including gloves and masks.” Tit. 26 Tex. Admin. Code § 746.3611. A “vaccine-preventable disease” is defined by Texas as “a disease that is included in the most current recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.” *Id.* § 746.3609. One of these diseases is COVID-19. CDC, COVID-19 ACIP Vaccine Recommendations, CDC (Nov. 5, 2021), <https://perma.cc/B2U6-GFYR> (hereinafter “CDC ACIP Recommendations”). All Head Start personnel in Texas are therefore likely already

required to be vaccinated for COVID-19, irrespective of the Rule.³

In turn, Head Start Programs have a responsibility to “ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program.” 45 C.F.R. § 1302.93(a). Current standards also include staff training on prevention and control of infectious diseases and establishing administrative procedures regarding protection from contagious diseases. 45 C.F.R. § 1302.47(b)(4)(i)(A) & (b)(7)(iii). Commonsense measures like demonstrably safe vaccines and masks are logically included in Head Start Programs’ preexisting obligations to prevent the spread of communicable diseases.

Current and past standards have also included regulations similar to the vaccine and mask requirements to avoid the spread of contagious diseases. In the past, standards have included spacing cribs three feet apart to avoid the spread of contagious diseases, 45 C.F.R. § 1304.22(e)(7) (2015), and temporarily excluding children with acute or short-term contagious illnesses, *id.* § 1304.22(b). Current regulations also require Head Start Programs to “[o]btain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventative and oral health care,” including following “immunizations recommendations issued by the Centers for Disease Control and Prevention,” *id.* § 1302.42(b)(1)(i), which currently include the COVID-19 vaccine for most Americans over age five, *see* ACIP Vaccine Recommendations. If a child is not up-to-date on vaccines, Head Start programs are directed to “[a]ssist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate

³ To the extent Plaintiffs may argue that there is a conflict between the Texas Standards and the executive orders issued by Governor Abbott related to COVID-19 vaccines referenced in their motion, *see* Br. 51, those arguments carry no weight. The Texas Standards were updated on November 10, 2021, *see* Minimum Standards for Child-Care Centers, Texas Health and Human Services Commission (Nov. 10, 2021), <https://www.hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/protective-services/ccl/min-standards/chapter-746-centers.pdf>, which was after Governor Abbott issued his executive orders related to vaccines between July 29, 2021 and October 22, 2021, and the Standards did not address any potential conflict.

provision of health services to bring the child up-to-date with parent consent.” 45 C.F.R. § 1302.42(b)(1)(ii). In order to accomplish this, Head Start programs are even permitted to “use program funds for professional medical and oral health services when no other source of funding is available.” *Id.* § 1302.42(e)(2).

All of the aforementioned health regulations, including those regarding vaccinations and communicable disease precautions, have been referred to as “performance standards” ever since 1975, and prior to this lawsuit, none of the Head Start performance standards had ever been challenged by anyone in the entire country. In fact, Plaintiff Lubbock Independent School District, which received its first Head Start grant in 1974, has abided by all of the Head Start Program Performance Standards, including the health standards such as health screening for staff and vaccination rules for participants, for forty-seven years. LISD has never challenged the idea that those standards should be limited to exclude health. Similarly, although not named as a plaintiff in this action, Plaintiffs reference the anticipated burdens of compliance with the Rule on a Head Start program operated by Texas Tech University and submit a declaration of Eric Brentley, the Vice Chancellor and General Counsel of the Texas Tech University System, in support of their motion. The Court should not consider these references to alleged harm to a non-party like Texas Tech, but in any event, like LISD, Texas Tech has complied with all of the health and medical regulations discussed above since it received its first Early Head Start grant in 2004. Indeed, Texas Tech applied and entered into the Head Start program with the knowledge that those standards already existed. The State of Texas, too, has accepted Head Start even with the very same sorts of standards that it objects to here. Yet now, as Head Start regulations continue to evolve to meet the challenges of the greatest public health threat of the present day—the global COVID-19 pandemic—Plaintiffs oppose the same sorts of health measures with which they have always complied. Plaintiffs’ history of compliance without complaint further undermines Plaintiffs’ argument that the Secretary somehow lacks statutory authority for the similar

measures required in the Rule.⁴

3. Nothing in the Statute or the Nondelegation Doctrine Forecloses the Secretary's Reading of the Statute.

The agency's interpretation of the statute as including the authority to require masks and vaccinations is also likely to be given deference as reasonable because the statute does not clearly express otherwise. *See generally Gonzales v. Oregon*, 546 U.S. 243, 255–56 (2006) (*Chevron* deference is warranted “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority” (citation omitted)); *see also Florida v. Dep't of Health & Hum. Servs.*, No. 21-14098 (11th Cir. Dec. 1, 2021), Order at 15–16 (“The imposition of a vaccine mandate as a condition on the receipt of federal funds to ensure patient safety within those facilities is not expressly foreclosed by this statute. There appears little likelihood of success on the APA claim.”).

In discussing the Secretary's authority, Plaintiffs note the Supreme Court's statement that Congress must “speak clearly when authorizing an agency to exercise powers of ‘vast economic and political significance.’” Br. 21–22 (quoting *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam)). As explained above, however, Congress did speak clearly by authorizing the Secretary to impose, *inter alia*, “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress gave the Secretary the authority to adopt any “other standards as the Secretary finds to be appropriate.” 42 U.S.C. § 9836a(a)(1)(E). “Congress could have limited [the Secretary's] discretion in any number

⁴ Given the long history of these sensible health precaution requirements at Head Start facilities, including vaccinations, and Plaintiffs' willing compliance with all of them, it is unusual that Plaintiffs now argue that “Defendants' assertion of authority to issue a vaccine mandate under vague statutory language generally referencing health and safety creates a ‘serious danger,’ if allowed to stand, that Defendants will ‘choose to broadly exert power in a variety of contexts.’” Br. 14 (quoting *Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 934–35 (N.D. Miss. 2016)).

of ways, but it chose not to do so.” *Little Sisters of the Poor*, 140 S. Ct. at 2380. And courts may not “impos[e] limits on an agency’s discretion that are not supported by the text.” *Id.* at 2381. Plaintiffs can point to no statutory text that would indicate that Congress intended the broad powers it granted the Secretary over “administrative . . . standards,” “standards relating to the condition . . . of facilities,” and “such other standards as the Secretary finds to be appropriate” to mean anything other than their natural implication, which includes the protection of Head Start students and employees at federally-funded Head Start facilities from a virus that has killed more than 800,000 Americans. 42 U.S.C. § 9836a(a)(1)(E).

For this reason, Plaintiffs’ reliance on *Alabama Ass’n of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. There, the Supreme Court held that an eviction moratorium imposed by the CDC exceeded the agency’s authority to “prevent the [interstate] introduction, transmission, or spread of communicable diseases[.]” 42 U.S.C. § 264(a). Reading that language in context, the Court held that its scope was informed by the next sentence “illustrating the kinds of measures that could be necessary,” such as “fumigation” or “pest extermination.” 141 S. Ct. at 2488. Those measures “directly relate to preventing the interstate spread of disease,” whereas the eviction moratorium “relate[d] to interstate infection” only “indirectly,” through the “downstream connection between eviction” and possible spread of COVID-19 by evicted individuals who move “from one State to another.” *Id.*

Here, the connection between the vaccine and masking requirements and student and employee health and safety is clear and direct: By requiring program personnel and participants to take the measures that most effectively reduce the risk that they contract and spread the virus that causes COVID-19, the Secretary sought to reduce the risk that students and workers would contract the virus. *Cf. Florida v. Dep’t of Health & Hum. Servs.*, ---F.4th---, 21-14098, 2021 WL 5768796, at *12 (11th Cir. Dec. 6, 2021); *see generally Merck & Co. v. U.S. Dep’t of Health & Hum. Servs.*, 962 F.3d 531, 537–38

(D.C. Cir. 2020) (distinguishing an invalid rule with only “a hoped-for trickle-down effect on the regulated programs” from a valid rule with “an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs”). Moreover, should Head Start personnel and students become infected with COVID-19, all students’ ability to learn is hampered.

The other decisions which Plaintiffs urge this Court to consider discuss the enacting Congress’s perspective, declining to interpret ambiguous statutes to grant agencies sweeping powers on the theory that Congress should “speak clearly if it wishes to assign to an agency decisions of vast ‘economic and political significance.’” *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)). This case is entirely different for two reasons.

First, the Supreme Court’s decisions in *Utility Air*, *Brown & Williamson*, and *Alabama Ass’n of Realtors* all began with the statutory text and made clear that considerations of “‘economic and political significance’” are relevant only “‘if the text [is] ambiguous.’” *Alabama Ass’n*, 141 S. Ct. at 2489. In both *Utility Air* and *Brown & Williamson*, for example, the Court reasoned that adopting the agency’s position would have conflicted with other provisions of the very statute that the agency was interpreting. *See, e.g., Utility Air*, 573 U.S. at 321 (explaining that the agency’s position was “‘inconsistent with—in fact, would overthrow—the Act’s structure and design’”); *Brown & Williamson*, 529 U.S. at 141, 156 (explaining that the agency’s interpretation would be “‘incompatible’” with other aspects of the statute). Here, no such ambiguity or incompatibility exists, and Plaintiffs do not even purport to conduct a traditional textual and structural analysis.

Second, and in any event, the Secretary does not claim any “unheralded power to regulate ‘a significant portion of the American economy,’” *Utility Air*, 573 U.S. at 324 (quoting *Brown & Williamson*, 529 U.S. at 159), or “‘limitless authority to regulate health and safety,” Br. 14. Plaintiffs in this case are challenging a condition in a spending program, not an exercise of regulatory authority.

See supra at 7–8. The Secretary is simply exercising long-recognized and common sense power to adopt health and safety conditions for federally-funded programs for youth that are already subject to extensive conditions of participation. And there is no reason to think that Congress—which granted the Secretary broad authority to protect Head Start students and personnel precisely because it could not foresee all future threats to participant health and safety—would have regarded a vaccine or masking requirement as a matter requiring specific authorization. *See* 153 Cong. Rec. S14375-02-S14376, 2007 WL 3375993 (daily ed. Nov. 14, 2007) (statement of Sen. Edward Kennedy) (Head Start “provides the starting point for a child’s day, with a healthy meal each morning and a promise to parents that while they are at work and balancing two jobs, their children will see a doctor and dentist, and receive immunizations.” (emphasis added)). To the contrary, vaccine requirements have existed for centuries as a commonplace feature of American life, particularly in the education context. *See, e.g., Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (Easterbrook, J.), application for stay denied, No. 21A15 (Aug. 12, 2021). Head Start personnel already have to receive certain vaccinations and health screenings. *See supra* at 15–16. Thus, “when it comes to vaccination mandates, there was no reason for Congress to be more specific than authorizing the Secretary to make regulations.” *Florida*, 2021 WL 5768796, at *12 (in the context of the Secretary’s rulemaking regarding Medicare and Medicaid facilities). Basic hygiene practices like hand washing, disinfecting surfaces, and now wearing face masks to prevent the spread of viruses are similarly commonplace. In fact, Head Start regulations already require many of these practices. *See* 45 C.F.R. § 1302.47(b)(4)(i)(A) (staying home when sick); *id.* § 1302.47(b)(6)(i) (hand hygiene); *id.* § 1302.47(b)(2)(i) (cleaning, sanitizing, and disinfecting); *id.* § 1302.47(b)(4)(i)(A) (physical distancing). At a bare minimum, the Secretary reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See Northport Health Servs. of Ark., LLC v. U.S. Dep’t of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021).

Plaintiffs also invoke the nondelegation doctrine to contend that Congress could not delegate to the Secretary the authority to protect the health and safety of participants and employees at schools that receive Head Start funding. Br. 19. But “[d]elegations are constitutional so long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform.” *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (cleaned up), *cert. denied*, 141 S. Ct. 2746 (2021). The Secretary’s statutory authority to protect the health and safety of Head Start students and personnel easily meets this minimal standard. *Cf. Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 473 (2001) (upholding “public health” standard). The Secretary has been delegated authority in the Head Start Act merely to set standards for the performance of the Head Start program. Any performance standards that he implements under this statute, in addition to being “appropriate,” must of course further the purpose of the Head Start program. He is not regulating broad swaths of the economy. He is setting the terms on which grantees may accept federal funds. There is no nondelegation issue here.

4. Governments Have Historically Required Students and Educators to Obtain Vaccinations and to Employ Commonsense Measures to Prevent the Spread of Contagious Diseases.

Students and educators have long been subject to employer and State vaccination requirements, including for influenza and hepatitis B virus, among others. Indeed, “vaccination requirements, like other public-health measures, have been common in this nation.” *Klaassen*, 7 F.4th at 593 (holding that a state university vaccination requirement was among the “normal and proper” conditions of enrollment), *application for stay denied*, No. 21A15 (Aug. 12, 2021). The Supreme Court upheld the constitutional validity of such requirements and traced their historical roots more than a century ago. *See Jacobson v. Massachusetts*, 197 U.S. 11, 25–35 (1905) (identifying vaccine requirements in the United States and other Western countries in the early 1800s). Consistent with that history, many States have already established requirements for teachers and/or students to be vaccinated

against COVID-19 and to wear masks while in school. In fact, as already described, Texas's own Minimum Standards for Child-Care Centers appear to require child care program staff to be vaccinated for COVID-19 and for exempted employees to follow additional protective procedures, including wearing masks. *See supra* at 16. In light of this history, it is unsurprising that Congress did not expressly single out vaccination or masking requirements in its list of performance standards as it could have reasonably believed that such common health measures would fall within the Secretary's broad authority to issue health-related standards. *See Florida*, 2021 WL 5768796, at *12.

B. The Rule is Not Arbitrary and Capricious.

Plaintiffs' arbitrary-and-capricious claims fare no better. Agency action must be upheld in the face of an arbitrary-and-capricious challenge so long as the agency "articulate[s] a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made." *Little Sisters of Poor*, 140 S. Ct. at 2383 (citation omitted). A court's review is "narrow" and the court "is not to substitute its judgment for that of the agency." *Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Ky. Coal Ass'n v. TVA*, 804 F.3d 799, 801 (6th Cir. 2015) (APA standard is not an "invitation for judicial second-guessing"). Under this "deferential" standard, a court "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Critically, "mere policy disagreement is not a basis for a reviewing court to declare agency action unlawful." *N.C. Fisheries Ass'n, Inc. v. Gutierrez*, 518 F. Supp. 2d 62, 95 (D.D.C. 2007).

Here, the agency adopted a reasonable Rule after considering the relevant issues. The fifty-page Rule reasonably explains the agency's decision, setting forth the justifications, weighing costs and benefits, considering alternative approaches, and providing an economic impact analysis. *See generally* 86 Fed. Reg. at 68,052–68,101. Plaintiffs lodge a litany of conclusory claims that the Rule is arbitrary

and capricious. Br. 28–37. None of these claims has merit.

1. Plaintiffs first say that the agency’s decision to require masks for Head Start personnel while no requirement exists for staff in K through 12 schools “makes no sense.” Br. 29. However, ACF does not have authority to require masks for K through 12 staff. Head Start is a federally funded program for pre-K children only, so ACF can only implement standards for those personnel. These standards are binding on Head Start programs, regardless of state law. *See, e.g., City of New York v. FCC*, 486 U.S. 57, 63 (1988) (noting that federal regulations, like federal statutes, preempt state laws under the Supremacy Clause). To the extent that there are incongruities in the requirements at Plaintiffs’ schools, they are the result of the state and local school districts’ decisions not to implement mask requirements for K through 12 staff that align with the federal standards for Head Start.

2. Plaintiffs next argue that the agency acted arbitrarily and capriciously by “enforcing a vaccine mandate against Head Start staff” while “the federal government does not enforce the vaccine mandate against federal employees.” Br. 29. Plaintiffs’ motion contains no support for this proposition, but they appear to be referring to an allegation in the Complaint that, after the deadline for federal employees to be vaccinated had passed, the government “allowed federal employees an unspecified additional amount of time to ‘demonstrate progress towards becoming vaccinated’” rather than immediately terminate unvaccinated employees. Compl. ¶ 21. As an initial matter, there is no basis for holding a regulation of one agency arbitrary and capricious merely because another part of the federal government chooses to enforce a similar rule or regulation in a different way as applied to a different group of people, much less a rule that applies to the entire federal government workforce writ large. To the contrary, it is a “well known” principle of administrative law that regulations “are not arbitrary just because they fail to regulate everything that could be thought to pose any sort of problem.” *Pers. Watercraft Indus. Ass’n v. Dep’t of Com.*, 48 F.3d 540, 544 (D.C. Cir. 1995). ACF’s regulation should be upheld because the agency acted within the “zone of reasonableness,” *Prometheus*

Radio Project, 141 S. Ct. at 1158, irrespective of what other parts of the government are doing as to vaccination requirements in different contexts and for different populations. Federal employees who have not satisfied their obligation to be fully vaccinated are subject to discipline, including counseling, suspension, and, where noncompliance continues, removal or termination. *See* Safer Federal Workforce Task Force Guidance, <https://perma.cc/5F9G-H24C> (“Enforcement of Vaccination Requirement for Employees”). Here, the compliance date of January 31, 2022, for the Head Start vaccine requirement has not yet arrived, so HHS has had no need to take any enforcement action. Indeed, the Rule already provides some leeway akin to that granted to federal employees, stating that “for purposes of this regulation, staff, certain contract[or]s and volunteers will meet the requirement even if they have not yet completed the 14-day waiting period required for full vaccination.” 86 Fed. Reg. at 68,052.

3. Plaintiffs argue that the agency failed to consider “the adverse effects resulting from resignations of unvaccinated Head Start workers who do not want to be vaccinated” and “the withdrawal of children from families who do not want to wear masks.” Br. 29. To the contrary, the Rule takes these factors into account. It states that, “[t]o value the countervailing risk of staff vacancies, [ACF] adopt[s] an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks.” 86 Fed. Reg. at 68,091. The Rule also finds that, “[f]or each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings.” *Id.* One of the primary goals of the Rule is to reduce instances in which a positive case of COVID-19 in the classroom results in program closures and service interruptions. *See* 86 Fed. Reg. at 68,054. Thus, the agency considered that some personnel and students may voluntarily leave the Head Start program over the new requirements, but nevertheless determined that those costs would be outweighed by the benefits of reducing COVID-19 transmission. Courts are not to “second-guess[]” an agency’s “weighing of risks and benefits” associated with a rulemaking. *Dep’t of Com. v.*

New York, 139 S. Ct. 2551, 2571 (2019).

4. Plaintiffs relatedly argue that the Rule ignores “the interests of Head Start workers” who choose to remain unvaccinated “for any number of varying personal reasons.” Br. 29. As stated above, ACF did, in fact, consider that some Head Start personnel would refuse vaccination and may even resign from the program, and nevertheless found that the benefits of the vaccine requirement outweighed those costs. Additionally, the Rule provides exemptions from the vaccine requirement for personnel “who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” 86 Fed. Reg. at 68,061.

5. Plaintiffs next argue that the agency should have provided a “testing option” for personnel who refuse to comply with the vaccine requirement,⁵ noting in particular that the rule adopted by the Occupational Safety and Health Administration (“OSHA”) for private companies with over 100 employees allowed for this alternative. Br. 29–30. *See generally In re MCP No. 165, Occupational Safety & Health Admin.*, No. 21-4027, 2021 WL 5989357, at *1 (6th Cir. Dec. 17, 2021) (upholding the OSHA rule). In promulgating the Rule, ACF considered “screening and diagnostic testing” as one alternative approach. 86 Fed. Reg. at 68,066. ACF ultimately decided to require vaccinations and mask use instead because those are two of the most effective mitigation strategies, as supported by numerous studies cited by the agency, and because those requirements align with the program performance standards already in place for the Head Start program. *Id.*; *see, e.g.*, CDC, “Science Brief: COVID-19 Vaccines and Vaccination,” updated Sept. 15, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html> (cited at 86 Fed. Reg. 68,053 n.20); Fowlkes, et al., *supra* (cited at 86 Fed. Reg. 68,055 n.33); Delahoy, et al., *supra* (cited at 86 Fed. Reg. at 68,054 n.26). The fact that OSHA’s rule requires different

⁵ The Rule does require weekly testing for personnel who are exempt from the vaccine requirement. *See* 86 Fed. Reg. at 68,053.

standards is beside the point. As noted above, there is no rule that one agency acts arbitrarily and capriciously merely because a different agency has adopted a different approach to address a common health risk in a different context. As the Rule explains, the OSHA rule, which covers over 80 million employees nationwide, is promulgated pursuant to a different statutory authority from the Rule and covers a far broader array of workplace contexts. 86 Fed. Reg. at 68,061, 68,069. It is thus not surprising that the two agencies determined that different standards were appropriate for different situations.

6. Plaintiffs claim that the Rule is arbitrary and capricious because it does not “provide an exemption to persons with natural immunity to COVID-19.” Br. 30. Plaintiffs state, without any support, that “natural immunity is at least as effective as vaccination in preventing re-infection, transmission, and severe health outcomes.” *Id.* The agency disagreed with Plaintiffs’ assertion, finding that “[t]he COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus.” 86 Fed. Reg. at 68,054–55. The Rule supports this finding with numerous scientific studies. *Id.* at 68,055 & nn.31–36. “When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.” *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983). ACF reasonably concluded that, based on the evidence, vaccinations are a superior mitigation strategy, regardless of a recipient’s supposed “natural immunity.”

7. Plaintiffs next argue that the Rule is pretextual and therefore arbitrary and capricious. Br. 30–31. They correctly cited many of the reasons that the Rule was adopted, as follows:

The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA. The Secretary considered the Office of Head Start’s past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing

children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures. The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.

Br. 30 (quoting 86 Fed. Reg. at 68,054). Plaintiffs then state that these reasons are pretextual, despite the ample support for these justifications throughout the Rule, and despite that the real reason the agency implemented the Rule is “because President Biden ordered it.” Br. 31. Even if Plaintiffs are correct that the agency was prompted by the President, there is nothing unusual or unlawful about this. “[A] court may not set aside an agency’s policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration’s priorities.” *Dep’t of Com.*, 139 S. Ct. at 2573. Unlike in *Department of Commerce v. New York*, here there is not a “significant mismatch between the decision the Secretary made and the rationale he provided.” 139 S. Ct. at 2575. The rationale provided in the Rule justifies the decision made, and Plaintiffs do not provide any explanation otherwise.

8. Plaintiffs argue that the fact that ACF adopted the Rule in November 2021, when vaccines had been authorized for nearly a year, suggests that the agency acted arbitrarily and capriciously. Br. 31. But the Rule explains the reasons for its change in approach. It notes that “ACF initially chose, among other actions, to allow Head Start programs to decide whether or not to require staff vaccination rather than require vaccination, to provide information on the COVID-19 vaccine . . . , and to emphasize that grant recipients can use” certain federal funds “to support staff in getting the COVID-19 vaccine.” 86 Fed. Reg. at 68,054. However, as the agency eventually determined after study over a period of time, “uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families.” *Id.* In particular, “the advent of the Delta variant and the potential for new variants,” and

the “return to fully in-person services” in January 2022, justified a more robust approach. *Id.* The Rule cites CDC data regarding the Delta variant, which led to an increase in the total number of COVID-19 cases in the latter half of 2021 and has “resulted in greater rates of cases and hospitalizations among children.” *Id.* at 68,053. It also notes that, on November 10, 2021, the CDC “issued updated guidance to early childhood education and child care (ECE) programs,” which, among other things, recommended “universal indoor masking for ECE programs for everyone aged 2 years and older.” *Id.* at 68,054. The changed circumstances, including the emergence of the Delta variant and the updated CDC recommendations shortly before ACF issued the Rule, justified the change of course. This is not unusual. “[A]gencies are expected to reevaluate the wisdom of their policies in response to changing factual circumstances.” *COMPTON v. FEC*, 978 F.3d 1325, 1335 (D.C. Cir. 2020). The delay between the authorization of vaccines and ACF’s implementation of the vaccine requirement is therefore reasonable.

9. Plaintiffs argue that the Rule is arbitrary and capricious because it treats all communities alike, without regard to the specific rate of COVID-19 transmission in each. Br. 31–32. The Rule explains the agency’s decision, stating that “ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rates. For example, the requirement could make masking voluntary once community transmission drops below a certain level, consistent with CDC guidance.” 86 Fed. Reg. at 68,066. However, given the number of Head Start grant recipients and the fact that many serve entire states or cross state lines, “[t]ransmission rates could be significantly different across service areas.” *Id.* “It would be burdensome for” a grant recipient covering an entire state “to change its mask guidance for different centers through the state as transmission rates change.” *Id.* As such, “in the case of mask use, ACF is prioritizing a clear and

transparent policy that is easy for grantees to follow across their service areas.” *Id.*⁶

Plaintiffs also take issue with the fact that “[t]here is no end date or criteria for ending the universal mask mandate.” Br. 32. Again, the Rule provides a reasoned explanation: “[C]hildren benefit from routine and predictability. ACF determined that the best course of action was not to provide an end date on the” masking requirement and testing requirement for vaccine-exempt adults at this time. 86 Fed. Reg. at 68,066; *see Prometheus Radio Project*, 141 S. Ct. at 1158 (stating that the agency only needs to have “reasonably considered the relevant issues and reasonably explained the decision”). Additionally, ACF invited comments on this decision regarding an end date, indicating a willingness to adjust course if needed when it finalizes the Rule.

10. Plaintiffs contend that the Rule is arbitrary and capricious because “Defendants do not know how many staff and volunteers are already vaccinated.” Br. 32. The Rule estimated the current vaccination rate of Head Start staff based on a survey of 21,663 child care providers, including 1,456 individuals providing services through Head Start or Early Head Start. 86 Fed. Reg. at 68,069. The survey, conducted between May and June 2021, found that 73.0% of respondents had “received at least one dose” of the COVID-19 vaccine, compared to 65% of the U.S. general adult population at that time. *Id.* From this, ACF determined that Head Start staff are “about 12% more likely to be vaccinated than the general adult population.” *Id.* Extrapolating from CDC data on the vaccination rates for the total U.S. population, ACF modeled that Head Start staff were vaccinated at a rate of 77.1% on November 10, 2021. *Id.* at 68,070. The model also predicts the vaccination rate at future dates without a vaccine requirement based on the CDC data, estimating that 79.8% of Head Start staff would be vaccinated on March 1, 2022. *Id.* Because the goal of the Rule is to ensure that as many

⁶The four counties (McMullen, Kenedy, Sterling, and Borden) cited by Plaintiffs as having no recently reported COVID-19 cases, Br. 31, are sparsely populated and thus do not have a Head Start program, *see* Br. Ex. 2, ECF No. 8-1 at 53 (providing a list of Head Start programs in Texas). If a child in those counties wanted to attend a Head Start program, that child would need to travel to a different county, which would have a different COVID-19 transmission level.

Head Start personnel are vaccinated as possible, *see id.* at 68,077 (predicting that, in the long run, 5% of personnel will be granted an exemption and 95% of personnel will be vaccinated), ACF reasonably relied on this estimate to conclude that the current vaccination rate “has been insufficient to create a safe environment for children and families,” *id.* at 68,054. Additionally, part of the Rule implements a system for reporting vaccination status, so that the agency will have more accurate data on vaccination rates in the future. *See id.* at 68,061.

Plaintiffs confusingly manipulate a variety of numbers to undermine ACF’s straightforward statistical modeling. They note, from a different part of the Rule that models future coverage with a vaccine requirement, that the May to June survey found that 5.0% of unvaccinated respondents were “absolutely certain” to get the vaccine in the future and 6.9% were “very likely” to get the vaccine. Br. 32; *see* 86 Fed. Reg. at 68,077. Plaintiffs then appear to add 5.0%, 6.9%, and 73.0% to conclude that “the final vaccine uptake among child care providers may settle around 90%” without a vaccine requirement. This is wrong for three reasons. First, $5.0 + 6.9 + 73$ is 84.9, not 90. Second, Plaintiffs ignore that the 5.0% and 6.9% figures are only of those respondents *who reported being unvaccinated*, *i.e.* 5.0% of 27% (or 1.35%) and 6.9% of 27% (or 1.863%). Adding these values to the 73% who were already vaccinated yields 76.213%, which is not far from the 77.1% figure modeled by ACF.⁷ Third, Plaintiffs’ approach does not take into account that adults, including child care providers, may have changed their preferences between June and November for a variety of reasons, including the increased prominence of the Delta variant during that time period. Plaintiffs then go back to relaying data based on ACF’s extrapolation of CDC data (which are constantly updated, thus accounting for slight variations in numbers calculated at the time the Rule was written and present) to conclude that 80.2% of Head Start personnel were fully vaccinated when the Rule was published on November 30,

⁷ An additional 28.2% of unvaccinated respondents said they were “somewhat likely” to get vaccinated in the future, which accounts for slightly higher estimates. *See* 86 Fed. Reg. at 68,078.

2021. Br. 33.

Plaintiffs say that the agency “abruptly switch[ed] the modeling criteria” and conclude that the agency “do[es] not actually know” the vaccination rate among Head Start staff. *Id.* The Rule uses a single model, described above, to estimate the vaccination rate as of November 2021. 86 Fed. Reg. at 68,069. The agency reasonably relied on this estimate in determining that the vaccine requirement was necessary.

11. Plaintiffs state that the mask requirement is arbitrary and capricious because the agency did not consider conflicting evidence from the World Health Organization (“WHO”) and the United Nations Children’s Fund (“UNICEF”). Br. 34. According to Plaintiffs, these organizations report that children ages five and under should not be required to wear masks based on the safety and interests of the child and “the capacity to appropriately use a mask with minimal assistance.” *Id.* The Rule instead relies on November 10, 2021 guidance from the CDC, which recommended “universal indoor masking for ECE programs for everyone aged 2 years and older” and found that “ECE program staff can model consistent and correct use for children aged 2 years or older in their care.” 86 Fed. Reg. at 68,054. It is reasonable for ACF to rely on the recommendation of CDC over competing information from non-governmental agencies. *See Balt. Gas & Elec. Co.*, 462 U.S. at 103 (recognizing that courts must be at their “most deferential” when reviewing an agency’s “scientific determination”); *N.C. Fisheries Ass’n, Inc.*, 518 F. Supp. 2d at 95 (“[M]ere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.”).

12. Plaintiffs argue that ACF acted arbitrarily and capriciously by not providing support for the decision to require children to wear a mask outdoors. Br. 34–35. The Rule cites and relies upon the November 10, 2021 updated CDC guidance. *See* CDC, “COVID-19 Guidance for Operating Early Care and Education/Child Care Programs” (Nov. 10, 2021), <https://perma.cc/Z6H8-EYGK> (cited at 86 Fed. Reg. at 68,054 & n.54). That guidance states that

“CDC recommends that people age 2 and older who are not fully vaccinated wear a mask in crowded outdoor settings or during activities that involve sustained close contact with other people.” *Id.* This recommendation matches precisely the outdoor mask requirement adopted by the Rule. *See* 86 Fed. Reg. at 68,053. The agency acted reasonably in relying on CDC recommendations over competing information from other organizations. Plaintiffs also state that the Rule “is arbitrary and capricious because it failed to consider evidence that doesn’t support masking children between the ages of two and five.” Br. 35. But Plaintiffs do not cite to any evidence that was before the agency. Further, Plaintiffs claim that the Rule only considered evidence concerning the effect masks have on adults and older children. *Id.* On the contrary, the CDC recommendation that the agency relied upon in adopting the Rule explains that children ages two and older should wear masks in certain settings. 86 Fed. Reg. at 68,054.

13. Plaintiffs argue that the CDC guidelines on which the Rule relies are “merely nonbinding recommendations and have never otherwise been imposed on Head Start programs.” Br. 35. This argument is meritless. Nowhere does the Rule suggest that ACF is *required* to implement a vaccine and mask requirement in accordance with CDC guidelines. Instead, ACF chose to rely on the scientific expertise of CDC in determining performance standards for Head Start.

14. Plaintiffs next argue that ACF failed to consider whether the mask requirement may stigmatize Head Start students, who are disproportionately from low-income and minority families, due to the fact that non-Head Start students may not be required to wear masks. Br. 35. Plaintiffs cite no evidence to support the assertion that mask wearing will lead to stigmatization, or that educators would allow the hypothesized behavior to occur. Moreover, the Rule explicitly considers its impact on underserved children and communities in particular:

Studies have shown that COVID-19 has disproportionately affected some racial and ethnic minority groups such as Hispanic or Latino, Black or African American, American Indian or Alaskan Native (AIAN), and Native Hawaiian and other Pacific Islander people. It is also estimated that these disparities may have long term

implications for these populations: for example, it is estimated that COVID-19 morbidity and mortality impacts can reverse over 10 years of progress in reducing the gaps in life expectancy between Black and White populations. Many families of Head Start children and staff are members of minority communities; 71 percent of families, and 69 percent of staff, self-identify as Hispanic/Latino, Black/African American, American Indian, or Alaska Native, who have been shown to be at increased risk of exposure to SARS-CoV-2. Given the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups, requiring vaccination among Head Start staff is not only an issue of personal health, but also promotes public and community health and health equity for children and staff in Head Start programs.

86 Fed. Reg. at 68,055–56 (footnotes omitted); *see also id.* at 68,058 (“Program closures [from positive COVID-19 cases] impede Head Start families from participating in the workplace, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.”).

15 Plaintiffs also argue that the Rule is arbitrary and capricious because the agency did not consider “the effectiveness of masking in preventing the spread of COVID-19 when mixing masked and unmasked children.” Br. 35–36. The Rule concludes that mask use is one of “the most effective mitigation strategies available to reduce transmission of SARS-CoV-2,” 86 Fed. Reg. at 68,053, and cites multiple studies demonstrating the effectiveness of mask use, *see id.* at 68,054. Thus, the Rule requires “universal” masking for all Head Start participants. *Id.* To the extent that Head Start students and non-Head Start students come into contact with one another, there is no study that suggest that masks lose all effectiveness at slowing the spread of SARS-CoV-2 merely because some unmasked individuals are present with masked individuals; to the contrary, evidence shows that a mask provides at least some protection to the wearer even when others around them are unmasked. *See, e.g.,* CDC, “Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure,” Feb. 19, 2021 <https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm>. Finally, as noted at the beginning of

this section, ACF's authority to implement a mask requirement does not extend beyond the Head Start program; if Plaintiffs are concerned about the incongruity present between classes at their schools, they can choose to implement mask requirements for K through 12 programs to align with the federal Head Start standards—or not—but they cannot dictate the federal standards.

16. Plaintiffs argue that the Rule is arbitrary and capricious because a study cited in the Rule does not justify the mask requirement. Br. 36. But Plaintiffs are mistaken about the purpose of the cited study; the study is not meant to justify the mask requirement specifically, but rather to provide background information that a variety of mitigation methods, including masks, have some degree of effectiveness at reducing the transmission of SARS-CoV-2. The Rule states that “during the period from September to October 2020, ACF collaborated with CDC to conduct a mixed-methods study in Head Start programs.” 86 Fed. Reg. at 68,056. “The study found that implementing and monitoring adherence to recommended mitigation strategies, *such as* mask use, can reduce risk for SARS-CoV-2 transmission in Head Start settings.” *Id.* (emphasis added). As Plaintiffs note, “[m]ask policies varied for children” in the programs studied. Br. 37 (alteration in original). That fact does not undermine the more general conclusion that various mitigation strategies, including masks (where used), demonstrated some effectiveness in the study. Elsewhere in the Rule, the agency cites a CDC brief in determining that masks are one of “the most effective mitigation strategies.” 86 Fed. Reg. at 68,066 & n.86. There is therefore no inconsistency between the cited studies and the propositions for which the Rule cites them.

17. Lastly, Plaintiffs claim that the Rule is arbitrary and capricious because a particular study that ACF considered does not justify the mask requirement in Plaintiffs' opinion. Br. 37. The Rule finds that “counties without school mask requirements experienced larger increases in pediatric COVID-19 case rates after the start of school compared to counties that had school mask requirements,” 86 Fed. Reg. at 68,056, and cites a study from July to September 2021, *id.* at 68,056

n.49. The problem with the study, Plaintiffs argue, is that it states that the findings contained therein “are subject to at least four limitations” in the statistical analysis conducted. Br. 37. There is no requirement under the APA that an agency only rely on perfect scientific studies, much less disregard studies that particular individuals or entities find unreliable. *See Prometheus Radio Project*, 141 S. Ct. at 1160 (noting that it is “not unusual” for an agency “not [to] have perfect empirical or statistical data”). Indeed many, if not most, statistical analyses have some limitations regarding sample size, etc., but that does not mean that they do not also provide valuable information upon which an agency may rely. *See generally* Richard Royall & Tsung-Shan Tsou, *Interpreting Statistical Evidence by Using Imperfect Models: Robust Adjusted Likelihood*, Journal of the Royal Statistical Society, Apr. 25 2003. In any event, this study is not the only source relied upon by ACF in adopting the mask requirement. As discussed above, ACF also relied on the CDC’s updated guidance. ACF “made a reasonable predictive judgment based on the evidence it had.” *Prometheus Radio Project*, 141 S. Ct. at 1160.

C. The Rule Does Not Improperly Rely on Existing Regulations.

Related to Plaintiffs’ arbitrary-and-capricious claims, Plaintiffs take issue with the portion of the Rule that discusses existing regulations for Head Start. Br. 23–28. But Plaintiffs misunderstand the purpose of this discussion. The existing regulations are cited in the section of the Rule entitled “Alternatives Considered,” and explains why ACF adopted a vaccine and mask requirement over other mitigation strategies, including “staying home if sick; handwashing; improving ventilation; screening and diagnostic testing; cleaning and disinfecting; keeping physical distance; and cohorting.” 86 Fed. Reg. at 68,066. This portion of the Rule was discussed in the previous section of this brief. *See supra* Section I.B.5. (explaining the lack of a “testing” option). The Rule explains that the vaccine and mask requirements were chosen for two reasons. 86 Fed. Reg. at 68,066. One is that these are “two of the most effective mitigation strategies available to reduce transmission of COVID-19.” *Id.* The other is that those requirements align with the program performance standards already in place for the Head

Start program. *Id.* The Rule states:

Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of § 1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which OHS sees as a strategy for a program's infection control practices). In addition, § 1302.47(b)(1)(iii) states that facilities need to be "free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety," though it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

Id.

The point of this discussion is not, as Plaintiffs suggest, to say that the already existing requirements "themselves justify the Vaccine Mandate and the Mask Mandate." Br. 23. Instead, this paragraph merely states that ACF already has a variety of program performance standards on health-related requirements, and a vaccine and mask requirement is not unusual given these existing standards. Plaintiffs go on to contend that the agencies' description of the regulations cited in this paragraph are not the best interpretation of the text of those regulations. Br. 24–25. These arguments are beside the point. As Plaintiffs recognize, this is not a case involving an "interpretive rule, or an informal interpretation of Defendants' own regulations." Br. 23–24. In other words, ACF is not requesting that the Court give deference to these interpretations of 45 C.F.R. § 1302.47 under *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). The precise contours of 45 C.F.R. § 1302.47 are not at issue in this case.

Plaintiffs also point to a statement in the background section of the Rule, which states that the "Head Start Performance Standards require children to be up to date on immunizations and their state's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a schedule to catch up." 86 Fed. Reg. at 68,059. Plaintiffs state that this is an incorrect interpretation of 45 C.F.R. § 1302.42. But that regulation, discussed *supra* Section

I.A.4., clearly states that a Head Start program must “[o]btain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventative and primary medical and oral health care,” including “immunization recommendations issued by the Centers for Disease Control and Prevention,” and must “[a]ssist parents with making arrangements to bring the child up-to-date as quickly as possible.” 45 C.F.R. § 1302.42(b)(1)(i), (ii);⁸ *see also Kisor*, 139 S. Ct. at 2414 (affirming that an agency’s interpretation of its own regulation is accorded deference). Again, though, the interpretation of § 1302.42 is beside the point because the Rule does not rely on this provision for the proposition that Plaintiffs claim it does. Plaintiffs assert that the regulation “does not justify requiring children to wear masks without parental consent.”⁹ Br. 26. But in the context of the Rule, the immunization requirements are discussed merely as background information in the economic analysis section. They are not themselves used to justify the mask requirement.

Plaintiffs repeat the same arguments with respect to the Rule’s background statement that “[i]t is equally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a)).” Br. 27 (quoting 86 Fed. Reg. at 68,059) (alteration omitted). Plaintiffs assert that 45 C.F.R. § 1302.93(a) applies only to staff members who “already have a communicable disease” and not to those who might become

⁸ The regulation also provides that “if necessary,” the Head Start program should “directly facilitate provision of health services to bring the child up-to-date with parent consent.” 45 C.F.R. § 1302.42(b)(1)(ii). Contrary to Plaintiffs’ assertion, Br. 26, the “parent consent” phrase only applies to the direct provision of health services by a Head Start program. It does not provide parents an opt-out of the immunization requirement. *See* Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,336 (Sept. 6, 2016).

⁹ As noted in the preceding footnote, “parental consent” in this context does not provide an opt-out of Head Start requirements. Indeed, by voluntarily enrolling their child in a Head Start program, parents are consenting to the performance standards laid out for the program, including those in the Rule.

“infected by an airborne virus” in the future. *Id.* The text of 45 C.F.R. § 1302.93(a) states that the Head Start program “must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program.” Plaintiffs’ reading of the regulation narrows its scope and contradicts the plain text, which applies to both pre-existing diseases and diseases Head Start personnel might contract. However, the interpretation of 45 C.F.R. § 1302.93(a) is not at issue, and contrary to Plaintiffs’ assertion, the Rule does not rely on this regulation to justify the vaccine requirement; it is cited for background purposes.

Finally, Plaintiffs note that the Rule relies on 42 U.S.C. § 9842 to justify the requirements for staff to document their vaccination status. *See* Br. 27–28; 86 Fed. Reg. at 68,061. Under this statute, “[e]ach recipient of financial assistance under this subchapter shall keep such records as the Secretary shall prescribe, *including*” various financial records. 42 U.S.C. § 9842(a) (emphasis added). Plaintiffs assert that this statute only authorizes recordkeeping of financial documents. However, the statute is broadly phrased to cover “such records as the Secretary shall prescribe.” *Id.* Notably, Head Start is a federal grant program, so every Head Start grantee is a “recipient of financial assistance under this subchapter,” *id.*, and the record-keeping provision should not be read narrowly so as to exclude non-financial records, *see In re Huckfeldt*, 39 F.3d 829, 831 (8th Cir. 1994) (“Use of the introductory word ‘including’ means . . . nonexclusive.”). ACF thus reasonably relied on this statute in determining that it could require documentation of vaccination status.¹⁰

D. The Secretary Had Good Cause to Issue the Interim Rule Without Advance Notice and Comment.

Notice-and-comment rulemaking is not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and

¹⁰ Plaintiffs do not appear to separately challenge the documentation requirement, only the vaccine requirement and the mask requirement. *See* Br. 1. As such, the arguments concerning 42 U.S.C. § 9842 are not reasonably related to the relief Plaintiffs seek.

public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B). While this exception is often narrowly construed, an agency “should have more latitude in determining when to invoke ‘good cause’ when notice and comment requirements are self-imposed.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). Such is the case here. The text of the APA exempts rulemakings “relating to . . . grants” from its notice and comment requirements, 5 U.S.C. § 553(a)(2), and Head Start is a “federal grant program,” Br. 2; *see also* 42 U.S.C. § 9831 *et seq.* HHS has previously issued internal guidance saying that it “will use notice of proposed rule making procedures in certain cases where not required by law.” Public Participation in Rule Making, 36 Fed. Reg. 2531, 2532 (Feb. 5, 1971). But because the text of the APA “clearly indicates congressional intent that notice and comment shall not be required, with the agency thus acting in an extra-statutory fashion by adopting the requirements as its policy,” the “congressional policy for interpreting good cause extremely narrowly does not operate.” *Alcaraz*, 746 F.2d at 612.

The Secretary properly waived notice and comment procedures under the good cause exception here. *See* 86 Fed. Reg. at 68,058–59. The exception excuses notice and comment where delay could result in serious harm. *See Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). The Secretary found that any delay in issuing the Rule would “endanger the health and safety of staff, children and families, and be contrary to the public interest,” 86 Fed. Reg. at 68,059, given the Rule’s “life-saving importance,” *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981). The emergence of the highly transmissible Delta variant, along with additional data showing the effectiveness of vaccines, amply justifies taking urgent measures. *See* 86 Fed. Reg. at 68,058. The Delta variant “has resulted in greater rates of cases and hospitalizations among children,” and in recent months, these rates have remained “elevated” compared to other points in the pandemic. *Id.* at 68,053, 68,055. Head Start involves young children under the age of five who cannot be vaccinated. *See id.* at 68,055. The 27% of Head Start personnel who are estimated to be unvaccinated “could result in

roughly 250,000 children who are in the care of an unvaccinated adult.” *Id.* at 68,056. Given the Delta variant’s “higher impact on children,” *id.* at 68,055, it is even more pressing that this potential for exposure is reduced immediately. *See Sorenson Comm’ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (although good cause is rarely invoked, “we have approved an agency’s decision to bypass notice and comment where delay would imminently threaten life”).

Moreover, the Office of Head Start’s anticipated “return to fully in-person services” in January 2022 further heightens the need for urgent COVID-19 safety measures. *See* 86 Fed. Reg. at 68,054. Temporary or intermittent closure of Head Start programs results in “harm to early learning and development” and “diminish[es] the ability of parents to work or participate in schooling.” *Id.* at 68,055. These programs meet children’s basic needs, such as meals and diapers, and ensure children maintain healthy everyday habits, such as brushing their teeth. *Id.* at 68,057; *see also Florida*, 2021 WL 5768796, at *14 (good cause exception properly invoked when Secretary identified “specific reasons” why the ongoing pandemic posed an immediate threat to a certain environment).

Additionally, referencing the COVID-19 surge in the winter of 2020, the Secretary highlighted the potential for infection rates to increase in the coming months due to cold weather, 86 Fed. Reg. at 68,058. The Rule also noted that “there is potential for the rapid and unexpected development and spread of additional new and more transmissible variants,” *id.* at 68,053. Given these recent developments in a rapidly-changing pandemic landscape, the Secretary was more than justified in taking immediate action on additional COVID-19 precautions—particularly for those regularly interacting with young children who cannot be vaccinated. *See Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) (“Stemming the spread of COVID-19 is unquestionably a compelling interest.”).

Rather than accept this reality, Plaintiffs again argue that the Secretary could have started his rulemaking earlier, given that “the vaccines have been available for nearly a year.” Br. 39. But the

Secretary “can and must be able to respond to dangers as they evolve.” *In re MCP No. 165*, 2021 WL 5989357, at *9. As noted, *see supra* Section I.B.8, the Secretary initially chose a policy of “allow[ing] Head Start programs to decide whether or not to require staff vaccination.” 86 Fed. Reg. at 68,054. Because of the Delta variant, an expected return to fully in-person services in January 2022, as well as a vaccination uptake among Head Start personnel that “has not been as robust as hoped for,” *id.*, the Secretary’s issuance of the Rule when he did does not undermine the application of the good cause exception.

Although Plaintiffs fault the Secretary for not immediately issuing the Rule when the President announced a plan to do so in September, the fact that the Secretary completed a fifty-page rule, with an analysis of over 144 cited sources, in roughly two months shows that he acted with appropriate dispatch in the face of the crisis. *Compare Asbestos Info. Ass’n/N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 423 (5th Cir. 1984) (recognizing that good cause may be met even when the agency acts years after learning of a serious health risk, so long as the agency “offer[s] some explanation of its timing in promulgating” the rule, and it “acted in response to new awareness of the danger”) *with* 86 Fed. Reg. at 68,052–68,101. Taking the time to craft a “reasoned policy determination” does not “undermine the state of emergency that this unprecedented pandemic currently presents,” *see In re MCP No. 165*, 2021 WL 5989357, at *9, especially given the number of issues the Plaintiffs claim the Secretary should have taken more time to consider, *see supra* Section I.B.

Because the Secretary had good cause to dispense with notice and comment rulemaking, Plaintiffs’ additional argument based on the Congressional Review Act is unavailing. 5 U.S.C. § 808 simply grafts the APA’s good cause standard onto the Congressional Review Act. Moreover, 5 U.S.C. § 805 “denies courts the power to void rules on the basis of agency noncompliance with the [CRA].” *Montanans for Multiple Use v. Barbouletos*, 568 F.3d 225, 229 (D.C. Cir. 2009).

E. The Rule Complies with 42 U.S.C. § 9836a(a)(2).

Plaintiffs also argue that the Rule violates a different section of the statute—42 U.S.C. § 9836a(a)(2). That section imposes two requirements on the Secretary’s development of any modifications to Head Start standards. First, it requires him to

consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs.

42 U.S.C. § 9836a(a)(2)(A). Second, it requires him to “take into consideration” nine different factors including such things as “past experience with the standards in effect,” “projected needs of an expanding Head Start program,” and “the unique challenges faced by individual programs.” *Id.* § 9836a(a)(2)(B). Plaintiffs argue that the Secretary violated both subparagraph A and subparagraph B because the Rule does not explicitly list each of the factors these subparagraphs require the Secretary to consider. *See* Br. 44–46. But notably absent from 42 U.S.C. § 9836a(a)(2) is any requirement that the Secretary document his consideration of each and every statutory factor using the exact wording of the statute. And to the extent Congress actually intended the Secretary to certify that he considered the specifically delineated factors, the Rule makes clear that he did just that: “In developing these modifications, the Secretary included relevant considerations pursuant to . . . 42 U.S.C. 9836a(a)(2).” 86 Fed. Reg. at 68,053–54.

While the Rule does not explicitly reference every factor in identical wording to that found in the statute, it includes ample explanation of the types of consideration the Secretary made, which clearly encompass the full breadth of the factors Congress intended him to consider under 42 U.S.C. § 9836a(a)(2). For example, Plaintiffs fault the Secretary for not fully documenting his consideration of “guidelines and standards that promote child health services and physical development, including participation in outdoor activity that supports children’s motor development and overall health and nutrition.” Br. 45 (quoting 42 U.S.C. § 9836a(a)(2)(B)(vi) (internal quotation marks omitted)). But in

fact the Rule explains, “The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children.” 86 Fed. Reg. at 68,060. So, actually, the Secretary did consider “child health services and physical development” including “outdoor activity.” 42 U.S.C. § 9836a(a)(2)(B)(vi). Plaintiffs complain that the Secretary did not explicitly spell out what he found to be the costs and benefits in this regard such as how wearing a mask under outdoor circumstances involving close contact with others might affect children’s physical development. Br. 45–46. But Plaintiffs’ complaint amounts to a disagreement with how the Secretary came out on this issue—not a valid claim that he did not consider the issue.

Similarly, Plaintiffs wrongly claim that the Secretary failed to “ensure that [the] revisions in the [program performance] standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” 42 U.S.C. § 9836a(a)(2)(C)(ii). Plaintiffs assert that “[n]o such analysis appears in the Interim Final Rule.” Br. 46. But in fact one of the Secretary’s primary reason for adopting the Rule was to insure the continuity of Head Start services, including the “health, educational, parental involvement, nutritional, social, or other services” such facilities provide. 42 U.S.C. § 9836a(a)(2)(C)(ii). ACF explained that the Secretary

considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

86 Fed. Reg. at 68,054. In any case, the Secretary noted that in the absence of reasonable measures like the Rule to prevent the spread of COVID-19, there would likely be intermittent closures of Head Start programs or even a switch to providing services virtually, *id.* at 68,055, which could reduce the quality, scope, or types of services offered to something below pre-2007 levels. The vaccine requirement does not change services from pre-2007 levels when tuberculosis screening, crib spacing,

and temporary exclusion were required for contagious disease control. *See supra* at 17. Rather, it updates the performance standards so they address the realities of the current environment, and therefore, support the continuation of the quality, scope, and types of services at the same or higher level as pre-2007. Plaintiffs' argument that the Secretary did not consider how revising the standards would affect Head Start services is meritless.

Finally, although Plaintiffs do not explicitly identify any particular factor they believe the Secretary incorrectly considered, they state that "[n]one of these factors that Defendants say they considered are factors that they must consider." Br. 45. To the extent Plaintiffs are arguing that the Secretary's consideration of factors not explicitly laid out in the statute is unlawful, that argument is also wrong. Nothing in 42 U.S.C. § 9836a(a)(2) indicates that Congress intended it to be an exhaustive list of all of the factors the Secretary may consider in promulgating new rules.

F. The Rule Complies with the Treasury and General Government Appropriations Act of 1999.

Plaintiffs' contention that the agency violated the Treasury and General Government Appropriations Act here by not conducting a family impact assessment, Br. 47, is a red herring. As an initial matter, that statute is plainly not judicially enforceable. *See* Public Law No. 105-277, 5 U.S.C. § 601 note (f) ("This section is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person."). But in any event, the agency explained that it had followed the requirements of that statute. Section 654 of that act requires agencies to first determine whether a policy or regulation "may affect family well-being" and then, only if the policy or regulation may do so, to "assess such actions with respect to" seven different criteria. The agency explained that it had followed the statutory requirement, stating, "ACF believes it is not necessary to prepare a family policymaking assessment . . . because the action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an institution." 86 Fed. Reg. at 68,062. The agency went on to "invite[] public comment on whether

the actions set forth in this interim final rule would have a negative effect on family well-being,” *id.*, thereby leaving the door open to a future family impact assessment if and when it might become necessary.

Plaintiffs fault ACF for failing to conduct this assessment that they argue is “mandatory” under the law, Br. 47, but tellingly, they do not argue that the Rule “may affect family well-being,” 5 U.S.C. § 601 note (f), explain how it might conceivably do so, or assert that it was arbitrary or capricious for the agency to make the determination that the Rule does not affect family well-being. Without arguing that the ACF was wrong to determine that the Rule would not impact family well-being, Plaintiffs cannot argue that the assessment was required.

It makes sense that Plaintiffs do not argue that the Rule may affect family well-being given that the Rule simply requires two commonsense measures while children are with their peers and personnel at Head Start facilities that are proven to slow the spread of a highly contagious virus. *See supra* at 5–6. When children are with their families at home or anywhere else, they are of course free to wear masks or not, as they so choose. The seven factors included in the family impact assessment plainly do not apply to the requirements of the Rule. For example, there is no reason to believe Congress intended ACF to assess whether vaccine and mask requirements “strengthen[] or erode[] the stability or safety of the family and, particularly, the marital commitment” or “increase[] or decrease[] disposable income or poverty of families and children.” 5 U.S.C. § 601 note. Because Congress plainly did not intend that agencies apply these factors to a rule like this one, and Plaintiffs do not so much as argue how any of these factors would apply to this Rule, Plaintiffs are not likely to succeed on the merits of this claim.¹¹

¹¹ Plaintiffs also argue that “Defendants limit the meaning of ‘family well-being’ . . . [to the] ‘autonomy or integrity of the family as an institution.’” Br. 48. That argument is irrelevant because Plaintiffs do not argue that this specific rule may affect *either* family well-being *or* the autonomy or integrity of the family as an institution. But at any rate, an agency is not required to mimic the text of

G. The Rule Complies with the Spending Clause.

Plaintiffs further contend that the Rule violates the Spending Clause, *see* Br. 49, which gives Congress the power to “lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and the general Welfare of the United States.” U.S. Const., art. 1, sec. 8, cl. 1. As interpreted by Courts, under that clause, if Congress “intends to impose a condition on the grant of federal moneys, it must do so unambiguously” so “States [can] exercise their choice knowingly.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981); *see also South Dakota v. Dole*, 483 U.S. 2030, 206–07 (1987). Plaintiffs’ Spending Clause claim fails for several reasons.

First, states do not receive the vast majority of Head Start funding. The Head Start Act only authorizes “*local* public or private” entities to be eligible for Head Start grants. 42 U.S.C. § 9836(a)(1) (emphasis added). While service providers for the Early Head Start programs need not be local, *see* 42 U.S.C. § 9840a(d)(3), Early Head Start comprises a far smaller amount of overall funding, *see* Congressional Research Service, Early Childhood Care and Education Programs: Background and Funding 12, (updated May 16, 2016) (noting that in 2015 the program included 87% Head Start enrollees and 13% Early Head Start enrollees).

Second, even on the rare occasions when states receive Early Head Start grants, as explained, Congress permits HHS to impose certain health and safety requirements upon those grants. *See supra* Section I.A.1. Congress “may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds.” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579 (2012) [hereinafter “*NFIB*”]. And any “consequences of imprecision” in spending legislation “are not constitutionally severe” when the Federal Government “is acting as patron rather than as

a statute verbatim in a simple statement in a rulemaking that it complied with it. *Cf. Breniser v. Shinseki*, 25 Vet. App. 64, 73 (Vet. App. 2011) (“Because the primary function of any regulation is to interpret the statute it implements, not mimic it, a regulation need not, and should not, parrot the statute it implements.”).

sovereign.” *See Nat’l Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998); *see also Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002) (“[T]he Supreme Court has held that conditions may be ‘largely indeterminate,’” and yet constitutionally permissible, as long as the States have clear notice that accepting funds “obligate[s them] to comply with [the conditions].”) (quoting *Pennhurst*, 451 U.S. at 24–25).

Third, the Rule unambiguously puts states on notice that they are obligated to comply with the mask and vaccine requirements when they receive Head Start funding. The Rule ensures that “the existence of the condition itself” will be “explicitly obvious” to grant recipients by clearly laying out the Rule’s three requirements: (1) universal masking for those two years or older; (2) vaccination for all Head Start personnel; and (3) weekly testing for those exempted from vaccination. *See Benning v. Georgia*, 391 F.3d 1299, 1307 (11th Cir. 2004) (citation omitted). A grant recipient will be capable of making “an informed,” voluntary decision whether to accept the attendant obligations of contracting with the Federal Government. *See Pennhurst*, 451 U.S. at 25. The challenged condition thus satisfies the Spending Clause.

H. The Rule Does Not Violate the Tenth Amendment or the Anti-Commandeering Doctrine.

Plaintiffs cannot succeed on their Tenth Amendment claim by simply invoking general maxims of federalism. The Tenth Amendment provides that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.” U.S. Const. amend. X. The powers specifically delegated to the federal government by the Constitution “are not powers that the Constitution ‘reserved to the States.’” *United States v. Comstock*, 560 U.S. 126, 144 (2010) (citation omitted); *accord New York v. United States*, 505 U.S. 144, 156 (1992) (“If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States[.]”). As long as federal action rests on a constitutionally delegated power, “there can be no violation of the Tenth Amendment.” *United States*

v. Mikbel, 889 F.3d 1003, 1024 (9th Cir. 2018) (citation omitted), *cert. denied*, 140 S. Ct. 157 (2019); *accord United States v. Hatch*, 722 F.3d 1193, 1202 (10th Cir. 2013).

As mentioned, 42 U.S.C. § 9836a(a)(1) was enacted pursuant to the Spending Clause, an evident exercise of Congress’s legislative power under the Constitution. *See Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 480 (1982). And where (as here) a federal statute is validly enacted under one of Congress’s enumerated powers, and the Executive Branch exercises authority lawfully delegated under that statute, the Tenth Amendment is no bar to federal action. Congress has charged the Secretary with the responsibility to ensure that federal funds are used in the way that Congress directed, and this includes the responsibility to protect the health and safety of those in the Head Start program. “Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, . . . [and] to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare.” *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates “in an area historically of state concern.” *Id.* at 608 n.*. The Secretary did not intrude on state police powers when he issued the Rule, then, any more than he did when he issued his long-standing rules conditioning federal funds on requiring that Head Start personnel do not “pose a significant risk of communicable disease.” 45 C.F.R. § 1302.93(a).

Moreover, “that states may regulate COVID-19 safety measures does not operate to preclude the federal government from doing so.” *See In re MCP No. 165*, 2021 WL 5989357, at *17. There is no general “doctrine implied in the Federal Constitution that the two governments, national and state, are each to exercise its power[s] so as not to interfere with the free and full exercise of the powers of the other.” *Case v. Bowles*, 327 U.S. 92, 101 (1946). Indeed, it is axiomatic that the federal government does not “invade[] areas reserved to the States by the Tenth Amendment simply because it exercises *its* authority” under the Constitution, even “in a manner that *displaces* the States’ exercise of their police

powers.” *Hodel v. Va. Surface Mining & Reclamation Ass’n*, 452 U.S. 264, 291 (1981) (emphasis added); accord *Okla. ex rel. Okla. Dep’t of Pub. Safety v. United States*, 161 F.3d 1266, 1272 (10th Cir. 1998). Thus, “‘the Federal Government, when acting within a delegated power, may override countervailing state interests,’ whether those interests are labeled traditional, fundamental, or otherwise.” *Brackeen v. Haaland*, 994 F.3d 249, 310 (5th Cir. 2021) (citation omitted), *cert. denied*, No. 21-380 (U.S. Sept. 8, 2021).

Plaintiffs also cannot establish a Tenth Amendment violation by asserting that states are “commandeer[ed]” into enforcing the Rule. *See* Br. 49–50. As the Supreme Court has explained, the Tenth Amendment’s anti-commandeering principle acknowledges a constitutional limitation of “the circumstances under which Congress may use the States as implements of [federal] regulation.” *New York*, 505 U.S. at 161. For example, the federal statute at issue in *New York* unconstitutionally “‘commandeer[ed]’ state governments” by forcing state legislatures or executive officials to enact state regulation according to Congress’s instructions. *Id.* at 175. In *Printz v. United States*, 521 U.S. 898 (1997), the federal statute “conscript[ed]” local law enforcement officials by requiring them to perform background checks in connection with firearms sales. *Id.* at 935. And in *Murphy v. National Collegiate Athletic Ass’n*, 138 S. Ct. 1461 (2018), the federal statute “commandeered the state legislative process” by “command[ing] state legislatures to . . . refrain from enacting [new] state law[s].” *Id.* at 1478–79.

The Rule does none of these things. For starters, whether a state chooses to participate in the Head Start program is entirely voluntary. Moreover, the statute authorizing the Office of Head Start to implement performance standards, 42 U.S.C. § 9836a(a)(1), was enacted under the Spending Clause. The Rule merely amends the conditions to which a Head Start participant must agree in order to receive grant funding. “[W]here Congress places conditions on a State’s receipt of federal funds—whether directly, or by delegation of clarifying authority to an executive agency—there is no commandeering of reserved State power so long as the State has ‘a legitimate choice whether to accept

the federal conditions in exchange for federal funds.” *New York v. Dep’t of Just.*, 951 F.3d 84, 115 (2d Cir. 2020) (quoting *NFIB*, 567 U.S. at 578).

II. Plaintiffs Will Not Suffer Irreparable Harm Absent an Injunction.

Plaintiffs also cannot demonstrate irreparable harm. When plaintiffs “fail[] to prove that, absent the injunction, irreparable injury will result,” the preliminary injunction “should be denied.” *Enter. Int’l, Inc. v. Corporacion Estatal Petrolera Ecuatoriana*, 762 F.2d 464, 472 (5th Cir. 1985). It is their burden to show that the harm of which they complain is likely and not merely possible. *Winter*, 555 U.S. at 20. “Speculative injury is not sufficient” “to make a clear showing of irreparable harm.” *Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985). Plaintiffs have not met their burden here.

Texas suffers no cognizable harm to its “sovereign interests” at all, let alone a harm of the type required for equitable relief. Br. 53–54. Absent an allegation that the State’s own enforcement efforts have been hampered, Plaintiffs do not have a cognizable interest for Article III purposes in the abstract question of whether state law is preempted, and so cannot claim imminent harm on that basis. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011) (“To permit a state to litigate whenever it enacts a statute declaring its opposition to federal law . . . would convert the federal judiciary into a ‘forum’ for the vindication of a state’s ‘generalized grievances about the conduct of government.’”) (quoting *Flast v. Cohen*, 392 U.S. 83, 106 (1968)). By its own terms, the Rule has a narrow scope and only preempts Texas’s laws with regard to children and personnel in the Head Start program. *See Florida v. Dep’t of Health & Human Servs.*, No. 3:21-cv-2722, ECF No. 18, Order at 6 (N.D. Fla. Dec. 1 2021) (declining to find preemptive effect as causing irreparable harm because “it is not a federal mandate that *all* Florida citizens must be vaccinated”). And “it is black-letter law that the federal government does not ‘invade[]’ areas of state sovereignty ‘simply because it exercises its authority’ in a way that preempts conflicting state laws.” *Florida*, 2021 WL 5768796, at *15 (quoting

Hodel, 452 U.S. at 291). As the Eleventh Circuit noted, to “conclude otherwise would mean that a state would suffer irreparable injury from all . . . federal laws with preemptive effect.” *Id.*

Texas’s real concern is not the preemption of its laws, but that the Rule purportedly harms a subset of its citizenry; namely, those involved in Head Start programs who do not wish to wear a mask or receive the COVID-19 vaccine. To the extent Texas seeks to litigate on its citizens’ behalf, it cannot do so. “A State does not have standing as *parens patriae* to bring an action against the Federal Government.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982). Accordingly, Texas cannot assert that it has been irreparably harmed based on such interests. *Cf. Texas v. Biden*, ---F. Supp. 3d---, 2021 WL 3603341, at *12 (N.D. Tex. Aug. 13, 2021) (Kacsmayk, J.) (contrasting a permissible suit in which a State asserts its own rights under federal law with one in which a State is impermissibly “attempting to protect its citizens from the *operation* of [the federal law]”); *Florida*, No. 3:21-cv-2722, ECF No. 18, Order at 7 (declining to find a *parens patriae* interest in a state law that operates to “shield employees who choose to work in a federally funded healthcare facility from the rules that govern administration of the federal program”).

Plaintiffs’ other claims of irreparable harm are entirely speculative. They rely on conjecture that the Rule “has the *potential* for a mass exodus” of staff and that parents “have stated that they do not want their children to wear masks,” so the school district “could *potentially* lose” students. Rollo Decl. ¶ 9 (emphases added). But “[t]here must be a *likelihood* that irreparable harm will occur. . . . [A] preliminary injunction will not be issued simply to prevent the possibility of some remote future injury.” *United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001) (quoting 9 Wright, Miller & Kane, *Federal Practice & Procedure: Civil 2D* § 2948.1 (3d ed.)). As discussed, the Secretary acknowledged that vaccination rates among Head Start personnel have “not been as robust as hoped for,” but he found—based on real-world experience with COVID-19 vaccination requirements in a variety of settings—that the vaccination Rule was likely to be highly successful, and that vaccine requirements

result in “substantial increases” in vaccine uptake. 86 Fed. Reg. at 68,054, 68,056; *see also* Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis, 86 Fed. Reg. 63,418, 63,422 (Nov. 16, 2021) (Office of Management and Budget analysis noting that “Tyson Foods reported more than 96 percent of its workforce is now vaccinated” after imposing a vaccination requirement). Plaintiffs also rely on an informal survey of teachers, some of whom indicate that they have not yet been vaccinated. *See* Br. Ex. 9, Decl. of Kathy Pearson ¶ 5, ECF No. 8-1. Merely noting that these individuals are not yet vaccinated does not mean that they are not *willing* to get vaccinated, or that Head Start personnel will resign because of the Rule in such numbers as to irreparably harm Plaintiffs’ Head Start programs. And to the extent that Plaintiffs rely on the “cancellation of grant funding” to demonstrate irreparable harm, “economic loss such as the loss of funding is not irreparable.” *Florida v. Dep’t of Health & Human Servs.*, --- F. Supp. 3d ---, 2021 WL 5416122, at *3 (N.D. Fla. Nov. 20, 2021); *see also Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981).

Plaintiffs also seize on the statement of a single teacher who says he would seek an alternative position if he were required to be vaccinated. Br. Ex. 8, Decl. of David Gray ¶ 4, ECF No. 8-1. But it is entirely unclear whether he would fall into one of the Rule’s exemptions from vaccination, which include those who “cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” 86 Fed. Reg. at 68,061. Plaintiffs provide no evidence about whether the teacher has requested an exemption, or what the status of his request is. In any event, the loss of employment of a single teacher to a large school district like LISD, which is all this declaration potentially demonstrates, cannot possibly constitute an irreparable harm to that school district.

Plaintiffs fare no better by relying on a statement from one parent whose child is not a Head Start participant, but who enrolls her child in a class with Head Start children. *See* Br. Ex. 7, Decl. of Allison Swafford, ECF No. 8-1. As explained, Texas does not have *parens patriae* standing, and accordingly, cannot litigate on behalf of any harm she has suffered individually. Any harm to Plaintiffs stemming from this one parent's voluntary withdrawal of her non-Head Start-enrolled child is far too attenuated to constitute irreparable harm. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013). And a rule requiring mask use is not irreparable in its own right because wearing an easily removable face covering is not an irreversible measure. *See Klaassen v. Trs. of Ind. Univ.*, ---F. Supp. 3d---, 2021 WL 3073926, at *42 (N.D. Ind. July 18, 2021) ("Wearing masks . . . [is]n't indicative of irreparable harm, but consistent with CDC guidelines"). For these reasons, Plaintiffs have failed to meet their burden of demonstrating that the Rule has caused them irreparable harm.

III. The Balance of Equities and Public Interest Overwhelmingly Favor Denying an Injunction.

The third and fourth requirements for issuance of a preliminary injunction—the balance of harms and whether the requested injunction will disserve the public interest—"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, these considerations tilt decisively in the Government's favor.

An injunction against the Rule would harm the public interest in slowing the spread of COVID-19 among young children in the Head Start program and those who come into close contact with them. *See In re MCP No. 165*, 2021 WL 5989357, at *19 (noting that the "costs of delaying implementation" of a COVID-19 vaccine requirement are "comparatively high"). In the context of this pandemic, "federal courts across the country have routinely concluded that undoing orders deemed necessary by public health officials and experts to contain a contagious and fast-spreading disease would result in comparatively more severe injury to the community." *Chambliss Enters., LLC v. Redfield*, 508 F. Supp. 3d 101, 123 (W.D. La. 2020) (citation omitted). In evaluating the balance of

harms, “courts properly decline to second-guess the judgments of public health officials.” *Id.* (internal citations omitted). Accordingly, numerous courts reviewing “executive action designed to slow the spread of COVID-19” have concluded that “[t]he public interest in protecting human life—particularly in the face of a global and unpredictable pandemic—would not be served by” an injunction. *Tigges v. Northam*, 473 F. Supp. 3d 559, 573–74 (E.D. Va. 2020); *see also, e.g., Am.’s Frontline Drs. v. Wilcox*, No. EDCV 21-1243, 2021 WL 4546923, at *8 (C.D. Cal. July 30, 2021); *Valdez v. Grisham*, ---F. Supp. 3d---, 2021 WL 4145746, at *13 (D.N.M. Sept. 13, 2021), *appeal filed*, No. 21-2105 (10th Cir. Sept. 15, 2021); *Harris v. Univ. of Mass., Lowell*, ---F. Supp. 3d---, 2021 WL 3848012, at *8 (D. Mass. Aug. 27, 2021), *appeal filed*, No. 21-1770 (1st Cir. Sept. 28, 2021); *Williams v. Brown*, ---F. Supp. 3d---, 2021 WL 4894264, at *10–11 (D. Or. Oct. 19, 2021); *Wise v. Inslee*, No. 2:21-cv-0288, 2021 WL 4951571, at *6 (E.D. Wash. Oct. 25, 2021); *Mass Corr. Officers Federated Union v. Baker*, ---F. Supp. 3d---, 2021 WL 4822154, at *7–8 (D. Mass. Oct. 15, 2021); *Johnson v. Brown*, ---F. Supp. 3d---, 2021 WL 4846060, at *26–27 (D. Or. Oct. 18, 2021); *Donovan v. Vance*, No., 4:21-CV-5148-TOR,--- F. Supp. 3d---, 2021 WL 5979250 at 7–8 (E.D. Wash. Dec. 17, 2021); *TJM 64, Inc. v. Harris*, 475 F. Supp. 3d 828, 840–41 (W.D. Tenn. 2020); *Talleywhacker, Inc. v. Cooper*, 465 F. Supp. 3d 523, 543 (E.D.N.C. 2020).

By comparison, any theoretical harm to Plaintiffs “pales in comparison to the significant loss of lives that Defendants have demonstrated could occur” if the Rule is enjoined. *Chambless Enters.*, 508 F. Supp. 3d at 123 (citation omitted). As explained above, *see supra* Section II, Plaintiffs’ claimed harms are speculative. Nowhere do Plaintiffs dispute the life-saving effects of vaccination. In fact, in discussing the public interest prong, they do not even acknowledge the unparalleled American casualties from COVID-19. Although they argue that the Rule will cause Head Start personnel to leave their jobs in large numbers, Plaintiffs have set forth no evidence to show that the vaccination rule will actually have that effect. As noted in the Rule, there are clear examples of requirements having exactly the effect that the Secretary intends—increasing the percentage of vaccinated personnel

to very high levels. *See* 86 Fed. Reg. at 68,056.

Moreover, “there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop.” *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008), *aff’d*, *Cornish v. Doll*, 330 F. App’x 919 (Fed. Cir. 2009). Congress has charged the Secretary with the responsibility to protect the health and safety of children participating in the Head Start programs. *See* 42 U.S.C § 9831(2); *id.* § 9836a(a)(1). The public interest favors allowing the Secretary to fulfill these responsibilities.

IV. Any Injunctive Relief Should Be Appropriately Limited.

If the Court disagrees with Defendants’ arguments, any relief should be no broader than necessary to remedy any demonstrated irreparable harms of the specific Plaintiffs in this case. “A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury,” *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs,” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Any relief should be limited in two respects.

First, any injunction should apply only to those aspects of the Rule for which the Court finds Plaintiffs have met their burden under the four-factor test for emergency relief. The Supreme Court has held a regulation severable where severance would “not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion.” *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of a regulation that exceeded the agency’s statutory authority). Severability clauses, such as the one in the Rule, *see* 86 Fed. Reg. at 68,060, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987).

Second, any injunctive relief should be limited, at most, to Head Start programs operated by

Plaintiffs. “The Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it.” *Gill*, 138 S. Ct. at 1933; *see also id.* at 1934 (citing *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)); *Madsen*, 512 U.S. at 765. Indeed, Plaintiffs have no interest in whether Head Start programs in other States or operated by other grantees are subject to the Rule during the pendency of this lawsuit nor standing to assert claims on behalf of programs in Texas that Plaintiffs do not operate. Plaintiffs’ claims would be fully redressed through a preliminary injunction prohibiting the Secretary from “implementing” or “enforcing” the Rule against only those programs that Plaintiffs themselves operate.

Nationwide relief would be particularly harmful here given that the only Plaintiffs in this action are Texas and the LISD and two other district courts are already considering similar challenges to the Rule as of the date of this filing. *See Brick v. Biden*, No. 2:21-cv-4386 (W.D. La. Dec. 22, 2021); *Louisiana v. Becerra*, No. 3:21-cv-4370 (W.D. La. Dec. 21, 2021). A nationwide injunction would render any forthcoming order by the district courts in *Louisiana* and *Brick*, as well as any additional orders that might follow from other courts that might consider similar claims, meaningless as a practical matter. Moreover, nationwide injunctions “take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); *see also Holland v. Nat’l Mining Ass’n*, 309 F.3d 808, 815 (D.C. Cir. 2002) (“Allowing one circuit’s statutory interpretation to foreclose . . . review of the question in another circuit” would “squench the circuit disagreements that can lead to Supreme Court review.”). Consistent with those equitable principles, the Fifth Circuit has repeatedly vacated or stayed universal injunctions that apply to nonparties, including in a matter decided just eight days ago with respect to another HHS vaccination requirement for the Centers for Medicare and Medicaid Services. *See Louisiana*, 2021 WL 5913302, at *2 (“This vaccine rule is an issue of great significance currently being

litigated throughout the country. Its ultimate resolution will benefit from ‘the airing of competing views’ in our sister circuits.”) (citation omitted); *see also Texas v. United States*, 14 F.4th 332, 341 (5th Cir. 2021); *Marshall v. Goodyear Tire & Rubber Co.*, 554 F.2d 730, 735 (5th Cir. 1977). There is no reason why Plaintiffs’ disagreement with the Rule should govern the rest of the country, portions of which undoubtedly welcome it as a lawful lifesaving measure.

CONCLUSION

For the foregoing reasons, Plaintiffs’ Motion should be denied.

Dated: December 23, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Madeline M. McMahon
MADELINE M. MCMAHON (DC Bar No.
1720813)
CHRISTOPHER EDELMAN (DC Bar No.
1033486)
MICHAEL P. CLENDENEN (DC Bar No.
1660091)
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street N.W.
Washington, DC 20005
Phone: (202) 305-1953
Fax: (202) 616-8460
madeline.m.mcmahon@usdoj.gov

Attorneys for Defendants